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MANUAL OF PATENT OFFICE PRACTICE

FOREWORD

Welcome to the *Manual of Patent Office Practice (MOPOP)*, a guide for patent examiners, applicants, agents and the public to the operational procedures and examination practices of the Canadian Patent Office.

Practices expressed in the MOPOP arise from the Office's interpretation of the *Patent Act*, *Patent Rules* and jurisprudence as of the date each chapter came into effect.

This manual is solely a guide and should not be considered to be a binding legal authority. In the event of any inconsistency between this guide and the applicable legislation, this legislation must be followed.

The manual will be updated periodically to reflect changes to the statutory, regulatory and jurisprudential framework governing patents in Canada. The revision date of a chapter is March 1998 unless otherwise indicated, and is listed on the Canadian Intellectual Property Office's web site at:

http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr00720.html.

Please note that the current version of the MOPOP does not cover all practices relating to the prosecution of applications filed prior to October 1, 1989.

Information regarding forthcoming updates to this manual, including periods of public consultation, may be found at:

http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr00758.html.

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Chapter 1
Contacting the Patent Office

1.01 Physical delivery of correspondence to CIPO

April 2018

For the purposes of sections 5 and 54 of the *Patent Rules*, correspondence addressed to the Commissioner of Patents may be physically delivered to the following address:

Canadian Intellectual Property Office
Place du Portage I
50 Victoria Street, Room C-114
Gatineau QC K1A 0C9

Correspondence delivered to the above address during ordinary business hours 8:30 a.m. to 4:30 p.m. (local time) will be considered to be received on the date of delivery.

Please be advised that once correspondence is received by CIPO it cannot be returned to the sender, even if the sender states that the correspondence was sent by mistake. Exceptionally, in cases where correspondence is related to a patent application that does not meet the requirements under subsection 28(1) of the *Patent Act* for obtaining a filing date, the documents will be returned to the sender.

The Fee Payment Form should always be submitted as a covering document and should be the only document submitted to CIPO that contains financial information, such as credit card numbers.

1.01.01 Designated establishments

For the purposes of subsections 5(4) and 54(3) of the *Patent Rules*, the following are the designated establishments to which correspondence addressed to the Commissioner of Patents may be delivered **in person**:

- Innovation, Science and Economic Development Canada
  C.D. Howe Building

235 Queen Street, Room S-143
Ottawa ON K1A 0H5
Tel.: 343-291-3436

8:30 a.m. to 4:30 p.m. (local time) Monday to Friday

- Innovation, Science and Economic Development Canada
  Sun Life Building
  1155 Metcalfe Street, Room 950
  Montreal QC H3B 2V6
  Tel.: 514-496-1797
  Toll-free: 1-888-237-3037

  8:30 a.m. to 4:30 p.m. (local time) Monday to Friday

- Innovation, Science and Economic Development Canada
  151 Yonge Street, 4th Floor
  Toronto ON M5C 2W7
  Tel.: 416-973-5000

  8:30 a.m. to 4:30 p.m. (local time) Monday to Friday

- Innovation, Science and Economic Development Canada
  Canada Place
  9700 Jasper Avenue, Suite 725
  Edmonton AB T5J 4C3
  Tel.: 780-495-4782
  Toll-free: 1-800-461-2646

  8:30 a.m. to 4:30 p.m. (local time) Monday to Friday

- Innovation, Science and Economic Development Canada
  Library Square
  300 West Georgia Street, Suite 2000
  Vancouver BC V6B 6E1
  Tel.: 604-666-5000

  8:30 a.m. to 4:30 p.m. (local time) Monday to Friday

Correspondence delivered during ordinary business hours to one of the designated establishments listed above will be considered to be received on the date of delivery to that designated establishment, only if it is also a day on which CIPO is open for business. Correspondence delivered to a designated establishment on a day when CIPO is closed for business will be considered to be received on the next day on which CIPO is open for business. For example, correspondence delivered to the designated establishment in Toronto on June 24 will not be considered received on June 24 since CIPO is closed for business. The correspondence will be considered received on the next day CIPO is open for business.

Please note that documents delivered to the addresses listed above must be enclosed in a sealed envelope.

1.01.02 Registered Mail™ and Xpresspost™ services of Canada Post

For the purposes of subsections 5(4) and 54(3) of the *Patent Rules* the Registered Mail™ and Xpresspost™ services of Canada Post are designated establishments to which correspondence addressed to the Commissioner of Patents may be delivered.

CIPO considers that correspondence delivered through the Registered Mail™ and Xpresspost™ services of Canada Post is received by CIPO on the day indicated on the mailing receipt provided by Canada Post, or if CIPO is closed for business on that day, on the day when CIPO is next open for business.

1.02 Electronic correspondence

April 2018

In accordance with section 8.1 of the *Patent Act*, and for the purposes of subsections 5(6), 54(5), and 68(3) of the *Patent Rules*, correspondence addressed to the Commissioner of Patents may be sent by facsimile, online or on an electronic medium only as provided in this Chapter.

In accordance with subsection 54(5) of the *Patent Rules*, the request for national entry is the only correspondence addressed to the Commissioner in respect of an international application that can be submitted online or on an electronic medium with the exception of sequence listings, applications prepared using the PCT-SAFE software or prepared using WIPO's ePCT online service as provided in this Chapter. Other correspondence submitted online or on an electronic medium in respect of international applications that have not entered the national phase will not be accepted.

Correspondence sent by facsimile or online to the Commissioner of Patents constitutes the original, therefore a duplicate paper copy should not be forwarded.

Correspondence delivered by electronic means of transmission, including facsimile, will be considered to be received on the day that it is transmitted if delivered and received before midnight, local time at CIPO on a day when CIPO is open for business. When CIPO is closed for business, correspondence delivered on that day will be considered to be received on the next day on which CIPO is open for business.

1.02.01 Facsimile

Facsimile correspondence addressed to the Commissioner of Patents may be sent to the following facsimile numbers:

- (819) 953-CIPO (2476) or
- (819) 953-OPIC (6742)

Facsimile correspondence that is sent to any facsimile number other than those indicated above, including those of a designated establishment, will be considered not to have been received.

The electronic transmittal report returned to you following your facsimile transmission will constitute your acknowledgment receipt. Confidentiality of the facsimile transmission process cannot be guaranteed. Please note that CIPO strongly discourages the use of a computer facsimile interface or internet-based facsimile services due to technical issues with reception.

When submitting a document by facsimile that also has a fee requirement, notification of the preferred mode of payment to be applied must be prominently displayed on the Fee Payment Form to ensure expedient processing.

The document presentation requirements set out in sections 69 and 70 of the *Patent Rules* apply to facsimile correspondence.

1.02.02 Online

Correspondence addressed to the Commissioner of Patents may be sent electronically using the relevant links below.

For the purpose of subsection 5(6) of the *Patent Rules*, correspondence addressed to the Commissioner may be sent electronically by accessing the following pages:

- filing an application (regular application);
- filing a request for national entry;
- filing an international application (PCT Safe or ePCT);
- general correspondence relating to applications and patents;
- maintaining the name of a patent agent on the register of patent agents; and
- ordering copies in paper, or electronic form of a document.

1.02.02*a* Canada as Receiving Office under the PCT: PCT-SAFE

Pursuant to PCT Rule 89*bis*, CIPO, in its role as a receiving Office, accepts the electronic filing of an international application prepared using the latest version of the WIPO's PCT-Safe software and applications prepared using WIPO's ePCT online service. Filing in both cases must be done using CIPO's International Filing e-service, called PCT E-Filing.

Note: Correspondence related to PCT international applications cannot be sent electronically to CIPO. Correspondence may be sent by mail, by facsimile or delivered by hand to CIPO or to a designated establishment.

1.02.03 Electronic medium

The Patent Office will accept correspondence on various types of electronic medium as specified below. The electronic medium should contain a table of contents and be provided with a cover letter, which will be date stamped by CIPO and placed in the application file. Filing date requirements prescribed in the *Patent Rules* still remain.

When submitted on an electronic medium, the parts of the application must be logically broken down in files, which are no larger than 25 megabytes.

With regards to sequence listings under Rule 111 of the *Patent Rules*, the electronic medium must be separate from any electronic medium which may be filed containing parts of the application itself or amendment(s) thereof.

1.02.03*a* Canada as Receiving Office under the PCT: Electronic Filing of Sequence Listings

Pursuant to PCT Rules 89*bis* and 89*ter*, and in accordance with Part 7 of the PCT Administrative Instructions, where an international application contains disclosure of one or more nucleotide and/or amino acid sequence listings, CIPO, in its role as a receiving Office, accepts that the sequence listing part of the description and/or any table related to the sequence listing(s) be filed, at the option of the applicant:

- only on an electronic medium in electronic form in accordance with section 702 of Part 7 of the PCT Administrative Instructions; or
- both on an electronic medium in electronic form and on paper in accordance with section 702 of Part 7 of the PCT Administrative Instructions;

provided that the other elements of the international application are filed as otherwise provided for under the PCT.

The sequence listing part of an international application filed in electronic form and related tables filed in electronic form shall comply with the relevant provisions of Annex C of the PCT Administrative Instructions respectively.

For this purpose the Canadian receiving Office will accept any electronic media specified in Annex F of the PCT Administrative Instructions. Where both the sequence listing and the tables are filed in electronic form, the listing and the tables shall be contained on separate electronic media, which shall contain no other programs or files.

For the purpose of processing the international application, the Canadian receiving Office requires two (2) additional copies of the electronic media containing the sequence listing and/or tables in electronic form, accompanied by a statement that the sequence listings and/or tables contained in the copies are identical to those in electronic form as filed.

For further details concerning the filing of sequence listings and/or tables in electronic form, including the labeling of the electronic media and the calculation of the international filing fee, refer to section 7 of the PCT Administrative Instructions.

1.02.03*b* Electronic media accepted by the Patent Office

The Patent Office will accept 3.5 inch diskette, CD-ROM, CD-R, DVD, DVD-R and any format as specified in Annex F of the PCT Administration Instructions.

The electronic medium must also be free of worms, viruses or other malicious content. Files with malicious content will be deleted.

1.03 Details concerning the electronic formats accepted

April 2018

In accordance with section 8.1 of the *Patent Act*, and for the purposes of subsections 5(6), 54(5), and 68(3) of the *Patent Rules*, the acceptable file formats for documents submitted electronically using the relevant links set out in section 1.02.02 of this Chapter or on electronic media are TIFF and PDF. In order to get a correspondence date, the office will accept documents initially filed in other formats provided they are viewable with the software "Stellent Quick View Plus 8.0.0". In these cases, the office will request the documents to be replaced by documents in PDF or TIFF and the submission of a statement to the effect that the replacement documents are the same as the documents initially filed.

Sequence listings can be initially provided in TIFF, PDF or in ASCII file formats. However, as a completion requirement according to section 94 of the *Patent Rules*, a sequence listing in the ASCII format compliant with the "PCT sequence listing standard" has to be submitted. Therefore, CIPO encourages applicants to submit the sequence listings in the ASCII format in the first place.

When applicable, the Patent Office will accept files in the TIFF, PDF and ASCII format when they comply with the following specifications:

TIFF Format:

- TIFF CCITT Group 4, single or multi-page, black and white;
- Resolution of either 300 or 400 dpi;
- The dimensions of the scanned/stored images should match that of the paper requirements, namely 8 ½" by 11" or A4.

PDF Format:

- Adobe Portable Document Format Version 1.4 compatible;
- Non-compressed text to facilitate searching;
- Unencrypted text;
- No embedded OLE objects;
- All fonts must be embedded and licensed for distribution.

ASCII

- Shall be encoded using IBM Code Page 437, IBM Code Page 932 or a compatible code page.

1.04 General information

April 2018

General information may be obtained by communicating with CIPO's Client Service Centre.

1.05 Statutory holidays

April 2018

- Time limits under the *Patent Act*
- Time limits under the Patent Cooperation Treaty
- Provincial and Territorial Holidays
- When CIPO's Offices are closed for business

1.05.01 Time limits under the *Patent Act*

In accordance with section 26 of the *Interpretation Act*, any person choosing to deliver a document to a designated establishment (including CIPO's offices in Gatineau, Quebec; an Innovation, Science and Economic Development Canada regional office or the Registered Mail™ and Xpresspost™ services of Canada Post) where a federal, provincial or territorial holiday exists, is entitled to an extension of any time limit for the filing of the document that expires on the holiday, until the next day that is not a holiday. It is to be noted, in respect of provincial and territorial holidays, that the entitlement to the extension is dependent on the establishment to which the document is delivered and not on the place of residence of the person for whom the document is filed or of their agent. For this purpose, documents transmitted to CIPO by electronic means, including by facsimile, would be considered to be delivered to CIPO's offices in Gatineau, Quebec.

CIPO has no practical way of keeping track of the establishment to which documents are delivered. Accordingly, where a person has a time limit for the filing of a document that expires on a provincial or territorial holiday but only delivers the document on the next day that is not a holiday, CIPO will assume that the document was delivered to an establishment that would justify an extension of the time limit. In such circumstances, it will be the responsibility of the person filing the document to ensure that he or she is properly entitled to any needed extension of the time limit.

In addition to the extensions of time limits referred to above, in accordance with subsection 78(1) of the *Patent Act* any patent time limit that expires on a day when the Patent Office is closed for business is deemed to be extended to the next day when the Patent Office is open for business. All persons are entitled to these extensions regardless of their place of residence or of the establishment to which documents are delivered.

1.05.02 Time limits under the Patent Cooperation Treaty

Rule 80.5 of the Regulations under the PCT provides:

If the expiration of any period during which any document or fee must reach a national

Office or intergovernmental organization falls on a day:

i. on which such Office or organization is not open to the public for the purposes of the transaction of official business;

ii. on which ordinary mail is not delivered in the locality in which such Office or organization is situated;

iii. which, where such Office or organization is situated in more than one locality, is an official holiday in at least one of the localities in which such Office or organization is situated, and in circumstances where the national law applicable by that Office or organization provides, in respect of national applications, that, in such a case, such period shall expire on a subsequent day; or

iv. which, where such Office is the government authority of a Contracting State entrusted with the granting of patents, is an official holiday in part of that Contracting State, and in circumstances where the national law applicable by that Office provides, in respect of national applications, that, in such a case, such period shall expire on a subsequent day;

the period shall expire on the next subsequent day on which none of the said four circumstances exists.

CIPO takes the position that section 26 of the *Interpretation Act* applies to PCT international applications filed in Canada. Accordingly, where a person has a time limit under the PCT for the filing of a document in Canada that expires on a provincial or territorial holiday but only delivers the document on the next day that is not a holiday, CIPO will assume that the document was delivered to an establishment that would justify an extension of the time limit. CIPO, however, takes no position as to whether such extensions would be recognized by other countries, and it will be the responsibility of the person filing the document to ensure that in other countries of interest they are properly entitled to any needed extension of the time limit by reason of Rule 80.5 of the Regulations under the PCT or some other applicable law.

1.05.03 Provincial and territorial holidays

For the purposes of this practice notice, CIPO has identified the following as being days that are not federal holidays but that are holidays in one or more provinces or territories:

1. **Alberta**: Third Monday in February (Alberta Family Day)
2. **British Columbia**:
   - First Monday in August (British Columbia Day)
   - Second Monday in February (British Columbia Family Day)
3. **New Brunswick**: First Monday in August (New Brunswick Day)
4. **Newfoundland and Labrador**:
   - March 17 (St. Patrick's Day)
   - April 23 (St. George's Day)
   - June 24 (Discovery Day)
   - July 12 (Orangemen's Day)
   - First Monday in August (Regatta Day)
5. **Nova Scotia**: First Monday in August (Civic Holiday)
6. **Ontario**:
   - Third Monday in February (Ontario Family Day)
   - First Monday in August (Civic Holiday)
7. **Prince Edward Island**: First Monday In August (Civic Holiday)
8. **Quebec**: June 24 (St. John the Baptist Day)
9. **Saskatchewan**: First Monday in August (Saskatchewan Day)
10. **Yukon**: Third Monday in August (Discovery Day)

1.05.04 When CIPO's Offices are closed for business

For the purposes of subsection 78(1) of the *Patent Act*, CIPO's Offices are closed for business on the following days:

- All Saturdays and Sundays
- New Year's Day (January 1)*
- Good Friday
- Easter Monday
- Victoria Day: First Monday immediately preceding May 25
- St. John the Baptist Day (June 24)*
- Canada Day (July 1)*
- Labour Day: First Monday in September

- Thanksgiving Day: Second Monday in October
- Remembrance Day (November 11)*
- Christmas Day (December 25)*
- Boxing Day (December 26)

If December 26 falls on a Saturday, CIPO's Offices will be closed on the following Monday. If December 26 falls on a Sunday or Monday, the Offices are closed on the following Tuesday.

*If any of these holidays fall on a Saturday or Sunday, the Offices will be closed on the following Monday.

1.06 Procedures in case of an unexpected office closure at CIPO

April 2018

In case of an **emergency**, CIPO will attempt to remain open for business and ensure that essential service to our clients continues with the least possible disruption or delay. In view of the **date-sensitive nature** of intellectual property (IP), clients are advised to address important deadlines ahead of time to minimize the risk of affecting their IP rights. For the purposes of such deadlines, unless otherwise notified, clients should assume that all due dates remain in effect.

Whenever CIPO is closed for business, including closures due to extraordinary circumstances, CIPO considers **all time limits to be extended until the next day that it is open for business**. In such situations, mail delivered to CIPO or to the designated establishments will be considered to be received on the date that CIPO re-opens for business, with the exception of correspondence addressed to the Registrar of Topographies.

There may also be instances in which the designated establishments may be temporarily closed, yet CIPO remains open for business. In such situations, it remains the responsibility of CIPO's clients to ensure that all deadlines are respected.

Clients are **strongly encouraged** to send date-sensitive material through Canada Post by Registered Mail™ or Xpresspost™ or electronically using the relevant links set out in section 1.02.02 of this Chapter. Documents may continue to be faxed to CIPO at 819-953-CIPO (953-2476); however date-sensitive material requiring fee payment that is sent by fax must be accompanied by a VISA, MasterCard, or American Express credit card number, or CIPO deposit account number.

When possible during an emergency, information and search systems will continue to be available on our website; however, services provided through the Client Service Centre and other support areas within CIPO may be temporarily unavailable. Should an emergency occur, CIPO will post information on our service interruptions on CIPO's website as they become available and as circumstances permit.

1.07 Procedures when CIPO is open for business but clients are unable to communicate with the Office

April 2018

The legislative framework in relation with patents does not provide CIPO with the flexibility to extend deadlines when it is open for business but clients are unable to communicate with the Office.

In these situations it remains the responsibility of clients to ensure that all deadlines are respected.

The Office notes that Bill C-59 – Budget Implementation Act 2015, which received royal assent on June 23, 2015, contains provisions for extensions of time in Force Majeure-type situations (such as catastrophic events). However, these provisions have not yet come into force.

1.08 Interviews

April 2018

In some cases interviews may take place between examiners and the authorized correspondent or applicant. Where an agent has been appointed, the agent must be present at the interview or have authorized it. Such interviews will be documented in the

Canadian Patent Database.

1.08.01 Applicant-initiated interviews

Subject to the conditions imposed by subsection 6(3) of the *Patent Rules*, the authorized correspondent, applicant and agent may request an interview with an examiner in respect of an application. Appointments must be arranged in advance so that the examiner will be available and prepared to discuss the prosecution of the application. Where an agent has been appointed, the agent must be present at the interview or have authorized it.

An interview concerning the prosecution of an application, including an application that has received a final action, may be requested at any stage of the prosecution and will be conducted by the examiner in charge of the application. During the interview the examiner may provide further explanation about the defects identified in a report or clarify certain points concerning the invention. It should be noted that interviews do not replace the normal prosecution of an application. An examiner will not provide definitive verbal opinions or agree to accept amendments to the specifications during an interview.

In the case of an interview with a new examiner in training, a senior examiner or a section head will also be in attendance. Problems that do not concern the examination process are referred to the appropriate section of the Patent Office.

The Commissioner does not meet with applicants or agents about prosecution issues related to specific applications.

1.08.02 Examiner-initiated interviews

The Patent Examination Interview Service promotes direct communication between CIPO's patent examiners and patent agents or unrepresented inventors by allowing for the prosecution of patent applications by telephone. The Service encourages patent examiners to contact the authorized correspondent (i.e. the appointed patent agent or the inventor(s), in the case where no patent agent has been appointed) by phone in situations where advancing prosecution is likely, such as when there are only a few minor defects remaining in an application.

The Service offers the authorized correspondent the opportunity to discuss the application directly with the examiner, obtain suggestions or advice from the examiner as to how an identified defect may be overcome, and correct any identified defects through submission of a voluntary amendment within a predetermined timeframe. Any voluntary amendments submitted as a result of a phone interview are reviewed by the examiner expeditiously and the application is approved for allowance, if the application complies with the *Patent Act* and *Patent Rules*.

The predetermined timeframe above does not have any effect on the standing of the application; if a voluntary amendment is not received by the end of the predetermined timeframe, the examiner will simply issue a report based on the last received amendments.

1.09 CIPO Client Feedback

April 2018

As part of its ongoing commitment to improve its services, the Patent Office encourages clients to provide feedback using CIPO's online Client Feedback system.

Using this simple online form, clients may submit a complaint, comment or compliment. Those wishing to receive a response are invited to include their name and contact information. Feedback may also be submitted anonymously.

When a reply is requested, CIPO will provide an initial response within four business days. General matters are handled by CIPO's Client Service Centre. Questions or concerns of a more technical nature will be sent to the appropriate subject-matter expert within the Patent Office.

CIPO's online Client Feedback system is intended to help CIPO's clients provide comments on its services. Feedback is used to help CIPO resolve issues and to better understand how to improve its services.

It is important to note that the Client Feedback system is not intended for the prosecution of an application and cannot be used to respond to an official Patent Office requisition.

Chapter 2

Opening and inspection of applications

2.01 Inspection of applications

April 2014

In accordance with Section 10 of the *Patent Act*, all applications that have been opened to public inspection, protests when associated with an opened application file, prior art filed pursuant to Section 34.1 of the *Patent Act* when associated with an opened application file, patents and re-examination files, and all documents associated with any of the above, shall be available for inspection by request at the Patent Office or through CIPO's online ordering form (see chapter 1.07 of the MOPOP).

A patent application open to public inspection will be said to be "opened" or "laid-open" in this manual.

2.01.01 Opening of applications

All patent applications, except those filed prior to October 1, 1989 and documents on file in connection therewith, shall be open to public inspection after the expiration of an eighteen-month confidentiality period (subsection 10(2) of the *Patent Act*). The confidentiality period is one of

i) eighteen months from the Canadian filing date, or

ii) where a request for priority has been made, eighteen months from the earliest filing date of any previously regularly filed application on which the request for priority is based.

Applications filed under the Patent Cooperation Treaty (PCT) automatically include a designation for Canada. Such applications are published by the World Intellectual Property Organization (WIPO) eighteen months after filing or, where a request for priority has been made, eighteen months after the earliest priority date claimed. If an application enters the national phase after the WIPO publication date, the application and any documents on file in connection therewith will be available for inspection in the Patent Office at the time the application enters the national phase.

In accordance with subsection 10(2) of the *Patent Act*, an applicant may make a written request to have an application opened to public inspection before the expiry of the confidentiality period.

A listing of applications opened to public inspection each week will appear in the Canadian Patent Office Record..

A PCT application entering the national phase in Canada after the date of publication by the International Bureau of WIPO will bear, as the laid-open date, the date of publication of the international application.

2.01.02 Effect of withdrawal on opening of applications

An application will not be laid open to the public if it has been withdrawn at least two months prior to the expiration of the confidentiality period or a later date if the technical preparations to open the application to public inspection can be stopped (Sections 91, 92 and 145 of the *Patent Rules*).

2.01.03 Confidentiality of unopened applications

Unopened applications are confidential. Sections 10 and 11 of the *Patent Act* and sections 11, 91 and 92 of the *Patent Rules* apply. The Patent Office is required to protect applicants' interests by ensuring that only authorized persons are allowed to inspect unopened files. Applicants and authorized correspondents must provide identification when requesting access to a file. Persons permitted access by the authorized correspondent must provide identification and must furnish a signed document granting them authorization. The signed document must contain the patent application number and contact information of either the applicant or authorized correspondent, and must be signed by either the applicant or authorized correspondent. Inventors who have assigned all interest in their invention to others will not have access to an unopened file without authorization from the assignee or agent. If an agent has been appointed and the inventor has retained some interest in the application, the inventor may see the file and discuss the case with the examiner in general terms but, in accordance with subsection 6(3) of the *Patent Rules,* an interview including a detailed discussion of the prosecution is permitted only in the agent's presence or with the agent's consent. An examiner will not discuss matters relating to the prosecution of an application with persons other than the agent or those who have the agent's permission to discuss the application.

2.01.04 Effect of withdrawal of priority on opening to public inspection

A request for priority may be withdrawn at any time before a patent is issued. If the applicant withdraws a request for priority before the expiry of the confidentiality period it may be possible to delay the opening of the application to public inspection (subsection 10(4) of the *Patent Act*). The withdrawal must be made within sixteen months of the filing date of the priority application, or a later date if the technical preparations to open the application to public inspection can be stopped (sections 91 and 145 of the *Patent Rules*). The application will then be laid open to public inspection at the end of the new confidentiality period (eighteen months from the Canadian filing or eighteen months from the earliest of any other priority date, if more than one priority was claimed).

2.02 Numbering of applications

April 2014

An application for a patent filed after October 1, 1989 is given a unique number at filing. This number will be in the two million series of numbers and any patent issuing from such an application will bear the same number. A reissued patent and a re-examined patent will bear the same number as the original patent. Divisional applications are given a number in the two million series but different from the number of the original patent application.

Applications for patents filed prior to October 1, 1989 bear unique numbers. A patent issuing from such an application is given a unique number in the one million series. A divisional application arising from such an application will be given a number that is different from the number given to the original patent application. An application for reissue will also be given a unique number that differs from the original patent number.

2.02.01 Information relating to applications identified by serial numbers

On payment of the fee set out in Schedule II, item 24, the Patent Office will indicate whether a Canadian application identified by serial number has issued to patent.

2.03 Publications related to Canadian documents

April 2018

The *Canadian Patent Office Record (CPOR)* is published weekly every Tuesday. It contains a list of all the patent applications open for public inspection and all the patents granted for the week ending with the Tuesday of the publication, and it also contains important notices.

CIPO's Canadian Patents Database (CPD) provides access to the prosecution history and some administrative information relating to patent applications open to public inspection and relating to granted patents.

The complete prosecution history of an application or patent may also be viewed in person at CIPO's Gatineau office, purchased online via the Data and Document Dissemination Section, or obtained by contacting the Data and Document Dissemination Section at:

Data and Document Dissemination Section
Canadian Intellectual Property Office
Innovation, Science and Economic Development Canada
Place du Portage, Phase I
50 Victoria, Room C-229
Gatineau QC K1A 0C9
Tel.: 1 866 997-1936 (from 8.30 a.m. to 4.30 p.m. EST)
Fax: (819) 953-9969

2.04 Validity and interpretation of patents

April 2014

An issued patent granted by the Patent Office is presumed valid under section 43 of the *Patent Act* unless the Canadian court system decides otherwise or if the patent is made subject to reissue or re-examination procedures. Employees of the Patent Office may not comment on the validity of any issued patent, nor may they discuss how claims of any issued patent should be interpreted, or express a view as to whether they would be infringed by any proposal presented. Any member of the public requesting information of this type is advised to seek advice from a registered patent agent or a patent lawyer.

Chapter 3

Inquiries and information on pending applications

3.01 Inquiries by applicants

April 2014

Procedures for .inquiring about an application's status. can be found on CIPO's website.

3.02 Inquiries on pending applications (section 11 of the *Patent Act*)

April 2018

Notwithstanding the exception in section 10, on the request of any person who states in writing the name of the inventor, if available, the title of the invention and the number and date of a patent said to have been granted in a named country other than Canada, CIPO shall inform that person whether an application for a patent of the invention is or is not pending in Canada.

Requests under section 11 must be accompanied by the fee prescribed in Schedule II item 23 of the *Patent Rules*.

Chapter 4
Petitions and appointment of agents

4.01 Petition for grant of a patent

September 2014

The Petition for grant of a patent is a statutory requirement under subsection 27(2) of the *Patent Act* and must follow the form and instructions set out in Form 3 of Schedule I of the *Patent Rules* (section 77 of the *Patent Rules*), to the extent that the provisions of the form and the instructions are applicable. The petition must commence on a new page (section 72 of the *Patent Rules*), must not contain drawings (section 74 of the *Patent Rules*) and must conform to the specific requirements of document presentation set forth in section 68 of the *Patent Rules*.

While the abstract, description, claims and drawings of a patent application must be individually and all together wholly in English or wholly in French (subsection 71(3) of the *Patent Rules*), the petition may be in either English or French but does not have to be in the same language as the specification (section 71 of the *Patent Rules*).

As per section 61 of the *Patent Rules*, the requirement in subsection 27(2) of the *Patent Act* that an application contain a petition does not apply to applications filed under the provisions of the Patent Cooperation Treaty (PCT). These applications are filed with a request in accordance with Article 4 of the PCT.

4.01.01 Correction of clerical errors in the petition

The petition may be amended to correct clerical errors following a request under section 8 of the *Patent Act* or section 35 of the *Patent Rules*.

Note that section 35 of the *Patent Rules* can only be used prior to a patent being granted whereas section 8 of the *Patent Act* can be used either before *or* after a patent has been granted.

Note as well that in view of section 37 of the *Patent Rules*, if the error relates to the naming of an inventor or applicant, a corresponding corrected statement to the effect that the applicant is the inventor or declaration that the applicant is the legal representative of the inventor (if the applicant is not the inventor) might also need to be submitted. More information on the correction of clerical errors can be found in Chapter 23 of this manual.

4.01.02 Title of invention

The petition, i.e. Form 3 of Schedule I of the *Patent Rules*, must include the title of the invention.

That said, in accordance with paragraph 80(1)(a) of the *Patent Rules*, the description must also state the title of the invention, which shall be short and precise and shall not include a trade-mark, coined word or personal name.

In instances where the title of the invention in the description differs from the title in the Petition for Grant of a Patent, **the Office will only have regard to the title as specified in the description**. The application will grant to patent with the title as it appears on the first page of the description.

4.01.03 *Public Servants Inventions Act*

In the case of an invention by a public servant as detailed in sections 2, 3 and 4 of the *Public Servants Inventions Act,* the petition for patent must indicate that the inventor is a public servant.

4.02 Appointment of patent agents

September 2014

Individual inventors may prosecute or maintain their own applications as applicants provided they have not assigned their interest in the invention. This does not extend to successors in title. However, an inventor-applicant may choose to be represented by a patent agent residing in Canada whose name appears on the register of patent agents which permits the agent to act on behalf of the inventor-applicant. Whenever all or part of an inventor's rights have been assigned and the assignment has been recorded in the Patent Office, an application must thereafter be prosecuted by a registered patent agent residing in Canada (see sections 20, 21, 22, 23 and 24 of the *Patent Rules*). Whenever a patent agent is required but one has not been appointed, the Patent Office will send a notice to the applicant pursuant to section 23 of the *Patent Rules*. A patent agent must be appointed within three months from the date of the notice.

The appointment of a patent agent shall be made in the petition or by submitting to the Commissioner a notice signed by the applicant (subsection 20(2) of the *Patent Rules*).

It should be noted that all correspondence addressed to the Commissioner of Patents should be in accordance with section 5 of the *Patent Rules*.

The appointment of a patent agent can be revoked by submitting to the Commissioner a notice of revocation signed by the applicant or that patent agent (subsection 20(3) of the *Patent Rules*, see also sections 23, 24 and 40 of the *Patent Rules*).

4.02.01 Appointment of associate patent agents

A patent agent who does not reside in Canada cannot prosecute nor maintain an application, but must appoint an associate agent who resides in Canada to do so (subsection 21(1) of the *Patent Rules*). Whenever an associate patent agent is required but one has not been appointed, the Patent Office will send a notice to the agent pursuant to section 23 of the *Patent Rules*. An associate patent agent must be appointed within three months from the date of the notice. A patent agent who resides in Canada may also appoint an associate patent agent provided the associate patent agent also resides in Canada (subsection 21(2) of the *Patent Rules*).

Appointments of associate patent agents may be submitted by the applicant or the patent agent. Revocations of associate patent agents may be submitted by the applicant, the patent agent or the associate patent agent. (Subsections 21(3) and 21(4) of the *Patent Rules*.)

The appointment of an associate patent agent shall be made in the petition or by submitting to the Commissioner a notice signed by the patent agent who appointed the associate patent agent (subsection 21(3) of the *Patent Rules*).

The appointment of an associate patent agent can be revoked by submitting to the Commissioner a notice of revocation signed by the associate patent agent or the patent agent who appointed the associate patent agent (subsection 20(3) of the *Patent Rules* and section 23 of the *Patent Rules*).

4.03 Small entity declarations

September 2014

The term "small entity" is defined, in respect of an invention, as an entity that employs 50 or fewer employees or that is a university, but does not include an entity that (a) is controlled directly or indirectly by an entity, other than a university, that employs more than 50 employees; or (b) has transferred or licensed or has an obligation, other than a contingent obligation, to transfer or license any right in the invention to an entity, other than a university, that employs more than 50 employees (subsection 3.01(3) of the *Patent Rules*).

Where an applicant or patentee wishes to pay small entity fees, a small entity declaration must be submitted. A signed small entity declaration can be included in the Petition for grant of a patent (section 7 of Form 3 of Schedule I of the *Patent Rules*) at time of filing or can be submitted as a separate document at any time.

The Office will accept payment of fees at the small entity level in respect of an application or a patent only after a signed small entity declaration has been filed. The small entity declaration must be signed by either the applicant or the patent agent appointed by and on behalf of the applicant, and must indicate the name of the applicant and, if applicable, the name of the patent agent signing the declaration.

Where an application is not a PCT national phase application or a patent granted therefrom, an applicant or patentee is entitled to pay fees at the small entity level if, on the filing date of the application, the original applicant was a small entity in respect of the invention to which the application or patent is related. The original applicant is the applicant identified in the petition.

For a PCT national phase application or a patent granted therefrom, an applicant or patentee is entitled to pay fees at the small entity level if, at the date of national entry, the applicant entering the national phase was a small entity in respect of the invention to which the application or patent is related.

4.04 Representative drawing

April 2014

The applicant can request that a specific figure of the drawings, which is representative of the invention, accompany the abstract when it is made open to public inspection under section 10 of the *Patent Act*, provided a request to do so is included in section 8 of the petition (Form 3 of Schedule I of the *Patent Rules*) at the time of filing.

In the absence of such a request in the petition at time of filing, a single figure of the drawings will be selected by the Patent Office to be representative of the drawings illustrating an invention. This figure will be illustrated on the cover page of the patent application once it is made open to public inspection under section 10 of the *Patent Act*, and on the cover page of any patent which may issue from the application.

Chapter 5
Filing and completion requirements

5.01 Scope of this chapter - June 2015

This chapter applies to applications other than PCT national phase applications.

For applications filed under the provisions of the Patent Cooperation Treaty (PCT), see Chapter 22 of this Manual.

5.02 Filing of applications - June 2015

An application for a patent shall be addressed to "The Commissioner of Patents" and shall be considered to be received by the Commissioner (i.e. filed) on the date of reception [see section 1.04 of Chapter 1]. The requirements for receiving a filing date are set out in subsection 28(1) of the *Patent Act*.

Subsection 28(1) of the *Patent Act* provides that

> *The filing date of an application for a patent in Canada is the date on which the Commissioner receives the documents, information and fees prescribed for the purposes of this section or, if they are received on different dates, the last date.*

5.03 Requirements for a filing date - June 2015

To obtain a filing date under subsection 28(1) of the *Patent Act* an application must conform to the requirements of subsection 27.1(1) of the *Patent Rules*. It must include:

(i) an indication, in English or French, that the granting of a Canadian patent is sought,

(ii) the applicant's name,

(iii) the applicant's address or that of their patent agent,
(iv) a document, in English or French, that on its face appears to describe an invention, and

(v) either (A) a small entity declaration in accordance with section 3.01 of the *Patent Rules* and the small entity fee set out in item 1 of Schedule II as it read at the time of receipt, or (B) the standard fee set out in that item.

5.04 Completing the application - September 2017

Section 94 of the *Patent Rules* provides that even if an application has been given a filing date it remains incomplete unless it meets the requirements set out under subsection 94(2) of the *Patent Rules* at the time of filing.

Subsection 94(2) of the *Patent Rules* requires that certain information and documents, if not supplied at the time of filing, be supplied in order to complete the application. The requirements are that:

- the abstract, the description, the claims and the drawings comply with sections 68 to 70 of the *Patent Rules*, and

- the application contain the information and documents listed below:

    - a petition complying with section 77 of the *Patent Rules*,
    - an abstract,
    - a sequence listing complying with subsection 111(1) of the *Patent Rules* if a sequence listing is required by that subsection,
    - a claim or claims,
    - any drawing referred to in the description,
    - an appointment of a patent agent if required by section 20 of the *Patent Rules*, and
    - an appointment of an associate patent agent if required by section 21 of the *Patent Rules*.

In all cases of incomplete applications, the Patent Office will make every effort to inform the applicant of the reasons for noncompliance by means of a courtesy letter. The time limit to complete an application without paying the completion fee is the 15-month period after the filing date of the application or, if a request for priority has been made in respect of the application, the 15-month period after the earliest filing date of any previously regularly filed application on which the request for priority is based. The purpose of not requiring a fee for completing an application during the above period is to ensure that all documents listed above arrive at the Patent Office in a timely manner and in the proper format for laying open to public inspection under section 10 of the

Patent Act.

Pursuant to subsection 94(1) of the *Patent Rules*, if on the expiry of the applicable 15-month period the application is still not complete, the Commissioner shall, by notice to the applicant, requisition the applicant to complete the application and pay the fee set out in item 2 of Schedule II, before the expiry of the later of the 3-month period after the date of the notice and the 12-month period after the filing date of the application. Failure to complete the application or to pay the fee within the time period specified in the notice will result in abandonment of the application.

Chapter 6
Ownership, registration and joint inventors

6.01
Ownership – June 2015

A patent for an invention confers a property right on the inventor or in some cases on an employer of an inventor where the invention was made in the normal course of employment. Pursuant to sections 49 and 50 of the *Patent Act*, this right includes the entitlement to apply for a patent and such right may be transferred to another person at any time with proper documentation and payment of the fee set out in item 21 of Schedule II of the *Patent Rules*. As defined in section 2 of the *Patent Rules* a "transfer" means a change in ownership of a patent, of an application or of an interest in an invention and includes an assignment. Such a transfer may be effected at any time beginning at the date of invention and during the term of any patent which may issue in respect of that invention.

The history of transferring or passing on the right to a patent or an application is called the chain of title. The chain of title reflects any document that transfers ownership from the original applicant or any subsequent changes of owner. Such documents are, for example, assignments, mergers, change of name documents or wills.

By virtue of subsection 50(1) of the *Patent Act*, the owner of a patent may assign his right, either wholly or partially, either generally or subject to territorial limitations, and either for the whole term of the patent or for any part thereof. A patent right may be regarded as divisible as to content, territory, or time, and in each case the assignee is to be regarded as the owner of the part assigned, and the assignor as the owner of the part not assigned. Thus there may be more than one owner of the rights in a patent at one time.

6.02
Establishing entitlement at filing – June 2015

If the applicant is the inventor, pursuant to subsection 37(1) of the *Patent Rules*, in respect of both regularly filed patent applications and PCT national phase applications, the application must contain a statement to that effect.

Where the applicant is not the inventor, see 6.02.01 for regularly filed applications and 6.02.02 for PCT national phase applications.

6.02.01
Regularly filed patent applications

Pursuant to subsection 37(2) of the *Patent Rules*, in respect of an application other than a PCT filed application where the applicant is not the inventor, the application must contain a statement indicating the name and address of the inventor and a declaration that the applicant is the legal representative of the inventor. Pursuant to subsection 37(3) of the *Patent Rules*, the required statement or declaration shall be included in the petition or be submitted in a separate document. An assignment confirming entitlement can also be registered on a voluntary basis.

Pursuant to subsection 37(4) of the *Patent Rules*, if an application does not comply with the above requirements, the Commissioner shall, by notice to the applicant, requisition the applicant to comply with those requirements before the later of the expiry of the 3-month period after the date of the notice and the expiry of the 12-month period after the filing date of the application. If the applicant does not reply in good faith to this requisition, then pursuant to section 97 of the *Patent Rules*, the application will be deemed abandoned, and subject to the reinstatement provisions of the *Patent Act* and *Rules*.

Registration of an assignment is not required to establish entitlement at filing.

6.02.02
PCT national phase applications

Pursuant to subsection 58(5) of the *Patent Rules*, in respect of PCT national phase applications, where the applicant is not the applicant originally identified in the international application, the Commissioner shall requisition evidence that the applicant is the legal representative of the originally identified applicant where the documents already in the Patent Office do not provide such evidence.

Pursuant to subsection 58(5.1) of the *Patent Rules*, where the applicant does not comply with a requisition made by the Commissioner pursuant to subsection 58(5) within three months after the requisition is made, that applicant shall be deemed never to have complied with the requirements for their international application to enter national phase in Canada.

While not a requirement to enter national phase in Canada, pursuant to subsection 37(2) of the *Patent Rules,* the application must contain a declaration that the applicant is the legal representative of the inventor, or a declaration as to the applicant's entitlement, as at the filing date, to apply for and be granted a patent, in accordance with Rule 4.17 of the Regulations under the PCT.

As noted above, pursuant to subsection 37(4) of the *Patent Rules*, if an application does not comply subsection 37(2) of the *Patent Rules*, the Commissioner shall, by notice to the applicant, requisition the applicant to comply with those requirements before the later of the expiry of the 3-month period after the date of the notice and the expiry of the 12-month period after the filing date of the application. If the applicant does not reply in good faith to this requisition, then pursuant to section 97 of the *Patent Rules*, the application will be deemed abandoned, and subject to the reinstatement provisions of the *Patent Act* and *Rules*.

6.03
Registration of documents – June 2015

Pursuant to subsection 50(2) of the *Patent Act*, every assignment of a patent, and every grant and conveyance of any exclusive right to make and use and to grant to others the right to make and use the invention patented, within and throughout Canada or any part thereof, shall be registered in the Patent Office in the manner determined by the Commissioner.

Registration refers to the process of filing a document that is associated with a patent or an application. In accordance with section 42 of the *Patent Rules,* the Commissioner shall, upon request and on payment of the fee set out in item 21 of Schedule II of the *Patent Rules*, register in the Patent Office any document relating to a patent or an application [see 6.06].

6.04

Types of documents registered with the Patent Office – June 2015

Although any document associated with a patent or an application may be registered with the Patent Office, the types of documents registered typically fall into one of three categories:

- Transfers, including: assignments of all interest, assignments of partial interest, transfers of assets, court orders, wills, amalgamations, mergers and consolidations;
- Updates, including: changes of names, marriage certificates, changes of incorporation and affidavits; and
- Agreements, including: notice of license agreements, exclusive license agreements, license agreements, security agreements, debentures, compulsory licences and release of security agreements.

Registration provides a third party record of any ownership change relating to a patent or an application.

6.05

Requirements for registering a document (other than an assignment) – June 2015

In accordance with section 42 of the *Patent Rules,* the requirements for registering a document with the Patent Office are:

- a request to register the document;
- the document or a copy of the document to be registered;
- an indication of the patent application or patent to which the document relates; and
- the prescribed fee set out in item 21 of Schedule II of the *Patent Rules.*

6.06

Requirements for registering an assignment – June 2015

Assignments are the most common form of transfer registered by the Patent Office. References to assignments found throughout this chapter are intended to refer to transfers by contract. They are not intended to be inclusive of all types of transfer. For example, they are not intended to include transfers by inheritance, bequest or court order.

Assignments are often complex and diverse, frequently addressing matters reaching beyond intellectual property rights. The complexity of these documents may necessitate a significant effort by the Patent Office in order to ensure that the documented changes in title are accurately reflected in Office records.

Therefore, in order to assist the Office in its effort to simplify and expedite the processing of assignments while maintaining a high quality standard, the Office has developed forms for requesting the registration of assignments and strongly recommends their use.

The forms will be part of the record and will help ensure that all the required information has been submitted to the Office. The Office will use the content of the forms to assist with the registration of the assignment.

In the case where the forms are not used, the Office urges any requester to submit clear instructions. More specifically, in addition to the prescribed fee a request should include the following information, ideally on a cover sheet:

- the name of the assignor(s);
- the name and complete address of the assignee(s);
- the application or patent number against which the assignment is to be registered;
- specific information identifying which rights are being assigned and whether the interest in a right is being transferred in whole or in part.

A copy of the document effecting the transfer and either an affidavit or another proof satisfactory to the Commissioner that the assignment has been signed and executed must be submitted in accordance with sections 49 and 50 of the *Patent Act*. The following proofs are all considered to be satisfactory:

- with respect to a patent, a statement from the requester stating that, to their knowledge, the document effecting the transfer has been signed and executed by all parties;

- with respect to a patent application, a statement from the requester stating that, to their knowledge, the document effecting the transfer has been signed and executed by the assignor;
- a similar statement of a witness;
- the signature of a witness or the presence of a corporate seal on the assignment document;
- a document showing that the assignment was registered in a patent office of another country

Any document related to a change of ownership that is submitted to the Office will be registered; if, however, the information provided in the document does not meet the requirements to effect a transfer of ownership the Office will be unable to give effect to the change of ownership purportedly made in the document.

Note that all documents submitted to the Office will be made available to the public. Parts of these documents may contain personal information and applicants are encouraged to take steps to ensure that personal or sensitive information is omitted or obscured from the document before it is sent to the Patent Office.

6.07
Registration certificates – June 2015

Upon registration of a document with the Office, a certificate of registration is produced, identified by number and sent to the person who requested registration of the document. The documents submitted for registration are scanned and entered into the corresponding application file.

6.08
Maintaining chain of title – June 2015

In accordance with section 38 of the *Patent Rules*, no transfer of a patent or an application to a new owner shall be recognized by the Commissioner unless a copy of the document effecting the transfer from the currently recognized owner to the new owner has been registered and given effect in the Patent Office in respect of that patent or application.

Submitted assignment documents, associated forms and/or cover pages must refer to the person recorded as the registered owner/patentee at the time the document is filed. If the assignment document requests the assignment of rights of the recorded owner/patentee to an assignee, the Patent Office will amend its records to reflect this change. If it is noticed that the assignment document fails to refer to the registered owner or refers to an owner that does not correspond to the owner on record, the Patent Office will send a courtesy letter to the applicant indicating that the assignment document is not recognized by the Commissioner and will identify the deficiency.

6.09
Assignment correction mechanisms – June 2015

Occasionally, an error is present in an assignment (in the document effecting the change in ownership) and/or an error is made in the entry of information in the Patent Office's records.

A variety of errors can be corrected by filing an appropriate request. Such requests may be filed, depending upon the circumstances, by one of the parties to the assignment or by the applicant, owner, or legal representative on record.

It is important to note that despite the correction of an error, all documents that are registered by the Office will remain on record subject to a court order to the contrary.

6.09.01
Error in the records of the Patent Office

If the Patent Office has made an error in transcribing information into the Patent Office's records, the Office will correct the error upon request. The request must provide details regarding the error and must refer to the registered document. No fee is required for the correction.

6.09.02
Error in assignment document

In accordance with sections 49 and 50 of the *Patent Act*, the Office will proceed with the registration of an assignment provided that the request for registration complies with all procedural requirements. The Office takes the position, however, that an assignment may be registered without necessarily being recognized or, in other words, without being given effect. The Office will consequently not give effect to an assignment where it is satisfied that the assignment is invalid or where the assignor identified in the assignment does not correspond to the owner currently recognized by the Office.

Therefore, where an incorrect document has been registered or where a registered document contains a mistake, Office records may be updated to reflect the correct situation following the receipt of:

- a request for the registration of a newly submitted correct assignment, which complies with all formal requirements for the registration of an assignment; and
- an acceptable request to the effect that the previously registered assignment document (hereafter referred to as the "incorrect assignment") no longer be given effect.

To be considered acceptable, a request must always originate from one of the parties identified in the correct assignment.

The following additional requirements must also be met depending on the type of error to be corrected.

Where the error in the incorrect assignment does not relate to the name of the assignee the request must:

- contain a statement signed by the requester to the effect that the previously registered assignment contains a mistake and contain information describing the mistake.

Where the assignee mistakenly identified in the incorrect assignment does not exist or is the same entity as the assignee identified in the correct assignment the request must:

- contain a statement signed by the assignee identified in the correct assignment to the effect that:
    - the assignee was incorrectly identified in the previously registered assignment;

- the error in the incorrect assignment was due to inadvertence or mistake without any intention to mislead; and

either

- the incorrectly identified assignee does not exist; or
- the incorrectly identified assignee is the same entity as the assignee identified in the correct assignment.

Where the assignee mistakenly identified in the incorrect assignment exists and is different from the assignee identified in the correct assignment the request must:

- contain a statement signed by the mistakenly identified assignee to the effect that their name appeared in error on the incorrect assignment; and
- contain a statement signed by the assignee identified in the correct assignment to the effect that the error in the incorrect assignment was due to inadvertence or mistake without any intention to mislead.

This mechanism cannot be used after the grant of a patent to correct errors that were introduced during the application stage.

6.09.03
Clerical errors

Certain errors in assignment documents may qualify as clerical errors that arose in the mechanical process of typewriting or transcribing.

These errors may be corrected under section 8 of the *Patent Act* rather than via the mechanism set out above. A request for a correction under section 8 of the *Patent Act* should be accompanied by the required supporting information and the prescribed fee set out in item 19 of Schedule II of the *Patent Rules*. The supporting information required is an identification of the document of record in the Patent Office where the error occurs and a description of the clerical nature of the error.

If a request for correction under section 8 of the *Patent Act* has already been submitted but is not the appropriate mechanism, a new request will be necessary and will have to refer explicitly to the appropriate mechanism.

6.10
Joint inventors – June 2015

Inventions are frequently created as part of a collaborative effort. In such instances, all the inventors must join in applying for a patent.

Pursuant to subsection 31(1) of the *Patent Act*, if one of the inventors refuses to apply for a patent or his whereabouts cannot be ascertained after diligent inquiry, the other inventors or their legal representatives may apply for a patent, and a patent may be granted in the name of the inventors who apply for an application on satisfying the Commissioner that the joint inventor has refused to apply for a patent or that his whereabouts cannot be ascertained after diligent inquiry.

6.11
Adding and removing inventors – June 2015

An inventor may be added or removed at the written request of the authorized correspondent.

The Patent Office strongly recommends that the authorized correspondent provide an updated declaration of entitlement.

Note that the Office will not evaluate any evidence regarding ownership of the patent or patent application in the case of a disagreement between inventors and/or applicants.

6.12
Adding and removing applicants – June 2015

Pursuant to subsection 31(3) of the *Patent Act*, where an application is filed by joint applicants and it subsequently appears that one or more of them has had no part in the invention, the prosecution of the application may be carried on by the remaining applicant or applicants on satisfying the Commissioner by affidavit that the remaining applicant or applicants is or are the sole inventor or inventors.

Pursuant to subsection 31(4) of the *Patent Act*, where an application is filed by one or more applicants and it subsequently appears that one or more further applicants should have been joined, the further applicant or applicants may be joined on satisfying the Commissioner that he or they should be so joined, and that the omission of the further applicant or applicants had been by inadvertence or mistake and was not for the purpose of delay.

6.13

Jurisdiction of the Federal Court – June 2015

Pursuant to section 52 of the *Patent Act*, the Federal Court has jurisdiction, on the application of the Commissioner or of any person interested, to order that any entry in the records of the Patent Office relating to the title to a patent be varied or expunged, including the removal of a previously registered document.

Chapter 7
Requests for Priority

7.01 Scope of this chapter

May 2014

This chapter addresses the requirements for requesting priority from an application previously filed in Canada or in any country belonging to the Paris Convention for the Protection of Industrial Property ("the Paris Convention") or in any World Trade Organization (WTO) member country and the mechanisms for withdrawing priority from an application.

7.02 Priority

May 2014

Article 4 of the Paris Convention provides for the right of priority for patent applications filed in any country of the Union established by Article 1, section 1 of the Paris Convention. Article 2(1) of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights {TRIPS Agreement} provides that Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).

Claiming priority allows an applicant to benefit from a claim date that is earlier than the actual date of filing of the application. An applicant is required to file a request for priority to gain the earlier *claim date*. Priority is based on subject-matter disclosed in a priority document and is not restricted to what is *claimed* in the priority document[i]. A principal advantage provided by the right of priority is to give applicants time to decide whether they want to seek protection in one or more countries for an invention based on the filing of an earlier application (i.e. a priority document) in a country affording priority rights. This enables an applicant to disclose or publicly practice the later claimed invention between the filing of the priority document and the subsequent application. The effects of a request for priority are discussed in the context of the patentability of a claim in chapter 15 of this manual.

7.03 Requesting priority

The requirements for requesting priority in respect of an application for patent regularly filed[ii] in Canada are set out in section 28.4 of the *Patent Act*.
Section 28.4 of the *Patent Act* provides that

> *(1) For the purposes of sections 28.1, 28.2 and 78.3, an applicant for a patent in Canada may request priority in respect of the application on the basis of one or more previously regularly filed applications.*
>
> *(2) The request for priority must be made in accordance with the regulations and the applicant must inform the Commissioner of the filing date, country or office of filing and number of each previously regularly filed application on which the request is based.*

7.03.01 Right to priority

The right of an applicant to establish priority rights from an earlier application requires the application to meet the requirements of paragraph 28.1(1)(*a*) of the *Patent Act* and file a timely request in accordance with paragraphs (*b*) and (*c*).

Subsection 28.1(1) of the *Patent Act* provides that

> *The date of a claim in an application for a patent in Canada (the "pending application") is the filing date of the application, unless*
>
> *(a) the pending application is filed by*
>
> *(i) a person who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for Canada an application for a patent disclosing the subject-matter defined by the claim, or*
>
> *(ii) a person who is entitled to protection under the terms of any treaty or convention relating to patents to which Canada is a party and who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for any other country that by treaty, convention or law affords similar protection to citizens of Canada an application for a patent disclosing the subject-matter defined by the claim;*

> *(b) the filing date of the pending application is within twelve months after the filing date of the previously regularly filed application; and*
> *(c) the applicant has made a request for priority on the basis of the previously regularly filed application.*

An applicant may only file a request for priority based on a prior application that has also been filed by the applicant named on the pending application unless the person who filed the prior application has transferred priority to the requesting applicant (see section 7.03.02). That is, an applicant may not request priority based on an earlier application or applications filed by a different applicant unless the applicant named on the pending application is *successor in title* of the earlier application on the date the request is made under the provisions of Article 4 A(1) of the Paris Convention.[iii]

The prior application must have been filed in Canada or in any country belonging to the Paris Convention or in any World Trade Organization (WTO) member country to be afforded priority rights.

The applicant need not be a national of a Contracting Party of the Paris Convention but must either reside in, or have Areal and effective industrial or commercial establishments in the territory of one of the countries of the Union@.[iv]

7.03.02 Transfer of ownership

In situations where the rights conferred by a Canadian application or patent forming the basis of a request for priority for a later application have been transferred to a later applicant, the Office must have received a notice of transfer from the earlier applicant in accordance with section 38 of the *Patent Rules* which provides that

> *No transfer of a patent or an application to a new owner shall be recognized by the Commissioner unless a copy of the document effecting the transfer from the currently recognized owner to the new owner has been registered in the Patent Office in respect of that patent or application.*

Where the priority document is filed in a foreign jurisdiction and the applicant named on the priority document is different than the applicant for the Canadian application, the applicant in Canada must furnish the Office with evidence that priority rights have been transferred.

See chapter 6 of this manual for information on the requirements for transfer of rights.

7.03.03 Restoration of the right of priority is not available in Canada

"Restoration of the right of priority" is a mechanism used by the World Intellectual Property Office ("WIPO") and numerous countries whereby the time limit for filing an application accompanied by a request for priority is extended beyond the normal 12-month period after the filing of a priority document. This practice is limited to situations where the applicant failed to file a request for priority despite "due care" and where the failure to request was "unintentional" on the part of the applicant.

When acting as a Receiving Office for international applications, CIPO will accept a request by the applicant to restore the right of priority for an international application if it is satisfied that the criteria are met. This restoration may then be effective in designated Offices whose applicable national laws provide for restoration of the right of priority. As a designated Office, however, CIPO does not recognise requests for restoration priority.

In accordance with Rule 49ter.2 (h) of the PCT Regulations, the Office has informed the International Bureau that the restoration of priority rights is incompatible with the Canadian *Patent Act* and *Rules*. Consequently, the Office does not recognise extensions granted at the international phase for applications entering the national phase in Canada[v]. As the *Patent Act* and *Rules* do not contain provisions for restoring priority rights, regularly filed national applications are not subject to priority restoration.

7.03.04 Divisional applications and priority of parent application

The filing date of a divisional application filed in accordance with subsection 36(2) of the *Patent Act* is governed by subsection 36(4) of the *Patent Act* which provides, in part, that

> *A divisional application [...] shall have the same filing date as the original application.*

The Office automatically transfers any priority claim associated with the original application unless the applicant specifically requests that priority not be transferred by making an indication to this effect in section 4 of the Petition for Grant of a Patent ("the petition").

If an application is not entitled to divisional status, priority will not be considered as applicable to the pending application for examination purposes. The claim date of such an application will be the same as the resulting filing date, i.e., the date the documents were received by the Office, unless a valid request for priority is filed in accordance with the *Patent Act* and *Rules* as detailed in this chapter.

More information on divisional applications and priority can be found in MOPOP sections 14.10 and 14.13.

7.04 Rules governing requests for priority

May 2014

The requirements for establishing priority for applications filed on or after October 1, 1996 are set forth in subsection 88(1) of the *Patent Rules* and address single or multiple priority claims, treatment of priority documents filed before multinational authorities or through international treaties, and restrictions on time limits for requesting priority.

7.04.01 Requirements for making a request for priority

Paragraph 88(1)(*a*) of the *Patent Rules* provides that an applicant has the option of making a request for priority in the petition at the filing date or in a separate request. When a request for priority is not made in the Petition or where it is made on a date later than the filing date, the request must be made in accordance with paragraph 88(1)(*b*) or (c) of the *Patent Rules*. Failure to request priority in a timely manner will result in the claim date being the filing date conferred by section 28.1 of the *Patent Act*.

An applicant may not rely on any statement in the application - other than in the petition - which claims priority from an earlier application[vi]. For example, a statement in the introductory portion of the description claiming a benefit or priority from a United States application is not considered a valid request for priority even where the serial number and filing date have been provided; the same information must appear in the Petition or in a separate document to comply with subsection 88(1) of the *Patent Rules*.

7.04.01*a* Single priority document

Paragraph 88(1)(*b*) of the *Patent Rules* is applicable when the request for priority is based on a single document and provides that

> *where a request for priority is based on one previously regularly filed application, the request must be made, and the applicant must inform the Commissioner of the filing date, country of filing and application number of the previously regularly filed application, before the expiry of the sixteen-month period after the date of the filing of that application[.]*

Together, the filing date, country of filing and application number represent all of the information necessary for a successful request for priority from a single priority document and must be received by the Office no later than 16 months after the filing date of the priority document.

7.04.01*b* Multiple priority documents

Where multiple documents are relied on for a priority request, paragraph 88(1)(*c*) of the *Patent Rules* applies and provides that

> *where a request for priority is based on two or more previously regularly filed applications,*
>
> > *(i) the request must be made, and the applicant must inform the Commissioner of the filing date and country of filing of each previously regularly filed application on which the request for priority is based, before the expiry of the sixteen-month period after the earliest date of filing of those applications, and*
> >
> > *(ii) the applicant must, for each previously regularly filed application on which the request for priority is based, inform the Commissioner of its application number before the expiry of the twelve-month period after its date of filing or before the expiry of the period referred to in subparagraph (i), whichever is later.*

An applicant must provide the Office with the filing date and country of filing for each previously filed application from which priority is requested no later than 16 months after the filing date of the earliest previously filed application. For each previously filed application from which priority is requested, the applicant must furnish the Office with the application number no later than 12 months from the filing date of the corresponding previously filed application unless the 12-month limit occurs prior to 16 months after the filing date of the earliest previously filed application. In this case, the applicant would have until the expiry of the 16-month period to supply the Office with the application numbers for all priority documents.

Where a PCT application has benefited from restoration of priority rights at the international stage, the application will not receive the benefit of priority at the national stage and the applicant may forfeit certain rights for the application regardless of whether, in the case of multiple priority documents, other priority documents meet the normal criteria.

Example 1:

A regularly filed national application ('the pending application') is submitted to the Office on March 2, 2009. In the Petition, the applicant requests priority from a US application filed on March 3, 2008 and from a Canadian application filed on May 1, 2008. In item 4 of the Petition, the applicant provides the application number, the country of filing and filing date of the previously filed applications and requests priority from these prior applications.

Analysis:

The applicant is entitled to priority from both previously filed applications. The claim date of each claim in the pending application corresponds with the filing date of the previously filed application which first discloses the claimed subject-matter, i.e., either March 3, 2008 or May 1, 2008. The claim date for any subject-matter claimed in the application which is not found in either priority document is March 2, 2009.

Example 2:

A regularly filed national application is submitted to the Office on March 2, 2009. The applicant does not file a request for priority at filing but on July 15, 2009 files a request claiming priority from a US application filed on March 3, 2008 and from a Canadian application filed on August 1, 2008. The applicant provides the application number, country and filing date of the previously filed applications and requests priority from these prior applications.

Analysis:

The applicant is entitled to priority from the prior Canadian application filed on August 1, 2008, but not from the US application filed on March 3, 2008. The request for priority was filed later than 16 months after the *filing date* of the earlier US application and the request therefore does not comply with subparagraph 88(1)(*c*)(ii) of the *Patent Rules* in respect thereof. The applicant will receive priority based on the prior Canadian application.

7.04.02 Applications filed before an intergovernmental authority

Several intergovernmental organisations exist to centralize the patent search and examination process for a number of member countries. An applicant may request priority in Canada based on a previously filed application submitted to the intergovernmental organisation.

Subsection 88(3) of the *Patent Rules* provides that:

> *For the purposes of subsection (1), if the previously regularly filed application is for a patent granted by a national or an intergovernmental authority having the power to grant patents effective in more than one country, the applicant may provide the Commissioner with the name of the authority with which the application was filed instead of the country of filing.*

For example, an applicant seeking priority from an application filed at the African Regional Intellectual Property Organization (ARIPO) may identify the priority document by naming ARIPO as the authority[vii] and provide the filing date and application number issued by ARIPO.

7.04.03 Applications filed before an international organisation

International applications are filed before an international organisation which examines the application but does not issue a patent effective in any member state without further actions by the applicant to secure patent rights in elected states. These applications may form the basis of priority for applications filed in Canada.

7.04.03a Applications filed before the PCT

The filing of a PCT application has the effect of filing a regular national application[viii] in each state designated in the international application. The Canadian *filing date* of the national phase application is the same as the *filing date* for the corresponding PCT application. In accordance with the Paris Convention, the effect of an international application is equivalent to that of a national filing. Priority rights, for example, may be based on an international application.

Subsection 88(4) of the *Patent Rules* provides that:

> *For the purposes of subsection (1), if the previously regularly filed application is an international application, the applicant may provide the Commissioner with the name of the receiving Office with which the application was filed instead of the country of filing.*

For example, an international application may be filed directly with the International Bureau of WIPO. Such an application will be assigned an application number bearing the two-letter code 'IB'. Therefore, on filing a request for priority in Canada based on the internationally filed application, the applicant will identify the International Bureau as the receiving office and provide the application number assigned by the International Bureau.

If the international application has acquired priority rights before the International Bureau on the basis of an earlier filed application, those rights would be extended to the application upon national entry in Canada except in situations where restoration of priority rights has occurred (see section 7.03.03).

7.04.03*b* Applications filed before the European Patent Office

Under the authority of subsection 88(4) of the *Patent Rules* the Office acknowledges priority based on an application filed with the European Patent Office (EPO).[ix]

7.04.04 Extensions of time not permissible

While subsection 26(1) of the *Patent Rules* generally permits the Commissioner to grant extensions of time limits, subsection 88(5) of the *Patent Rules* provides that the Commissioner is not permitted to extend time limits for providing the Office information necessary to recognise a request for priority.

7.04.04*a* ***Dies non*** extension

Where the twelve-month anniversary date defined in paragraph 28.1(1)(*b*) of the *Patent Act* is a day when the Office is closed for business, the filing of the pending application may be made on the next day when the Office is open for business as provided by subsection 78(1) of the *Patent Act* without forfeiting priority rights.

7.05 Claim date based on multiple previously filed applications

May 2014

An application which claims priority from two or more prior applications may have multiple claim dates. Where an applicant has requested priority from two or more previously regularly filed applications, subsection 28.4(4) of the *Patent Act* provides that

> *(4) Where two or more applications have been previously regularly filed as described in paragraph 28.1(1)(a), subparagraph 28.2(1)(d)(i) or paragraph 78.3(1)(a) or (2)(a), either in the same country or in different countries,*
>
> *(a) paragraph 28.1(1)(b), subparagraph 28.2(1)(d)(iii) or paragraph 78.3(1)(b) or (2)(b), as the case may be, shall be applied using the earliest filing date of the previously regularly filed applications; and*
>
> *(b) subsection 28.1(2), subparagraph 28.2(1)(d)(ii) or paragraph 78.3(1)(d) or (2)(d), as the case may be, shall be applied using the earliest filing date of the previously regularly filed applications on the basis of which a request for priority is made.*

This has the effect of according the earliest possible claim date for subject-matter claimed in the pending application based on the content of the earliest corresponding priority document.

7.06 Withdrawal of a request for priority

May 2014

Under certain circumstances, an applicant may wish to withdraw a request for priority. This may be the case where, for example, the earlier application is withdrawn before publication or where the applicant has determined that later claimed subject-matter is not disclosed in the earlier application.

Subsection 28.4(3) of the *Patent Act* provides that a request for priority may be withdrawn at any time before a patent is issued[x] by filing a request with the Commissioner in accordance with subsection 90(1) of the *Patent Rules* which provides that

> *For the purposes of subsection 28.4(3) of the Act, an applicant may withdraw a request for priority, either entirely or with respect to one or more previously regularly filed applications, by filing a request with the Commissioner and the Commissioner shall send a notice to the applicant advising that the request for priority has been withdrawn.*

Under subsection 90(2) of the *Patent Rules*, the effective date of a request for withdrawal of priority is the date on which the Commissioner receives the request for withdrawal.

An application for which a Notice of Allowance has been issued may be subject to a withdrawal of allowance where the applicability of prior art under subsection 28.2(1) and section 28.3 of the *Patent Act* must be reconsidered as a result of the loss of priority.

7.06.01 Confidentiality

An application other than a PCT national phase application is not normally open to public inspection on the date the application is received by the Office.

A confidentiality period of up to 18 months is permitted in accordance with subsection 10(2) of the *Patent Act*. For applications accompanied by a request for priority, either at the time of filing in Canada or a later date (see section 7.04.01), the confidentiality period is dictated by subsection 10(3) of the *Patent Act*.

Subsection 10(3) of the *Patent Act* provides that

> *The confidentiality period begins on the filing date of the application or, where a request for priority has been made in respect of the application, it begins on the earliest filing date of any previously regularly filed application on which the request is based.*

The confidentiality period of an application filed in Canada ends 18 months after the filing date of the earliest priority document.

Subsection 10(4) of the *Patent Act* provides that

> *Where a request for priority is withdrawn on or before the prescribed date, it shall, for the purposes of subsection (3) and to the extent that it is withdrawn, be considered never to have been made.*

If the applicant withdraws a request for priority stemming from the earliest previously filed application before the expiry of the confidentiality period it may be possible to delay the laying open of the application to public inspection until 18 months from the next earliest priority date or, where no other priority documents exist, the filing date of the application.
Where the applicant seeks to withdraw a request for priority in respect of a non-laid open pending application, the applicant must ensure that the Commissioner receives the request for withdrawal before the end of the 18-month confidentiality period to avoid early publication of the pending application.

Section 91 of the *Patent Rules* provides that

> *For the purposes of subsection 10(4) of the Act, where a request for priority with respect to a particular previously regularly filed application is withdrawn in accordance with section 90, the prescribed date is the date on which a period of*

> *sixteen months after the filing date of that previously regularly filed application expires, or, where the Commissioner is able to stop technical preparations to open the application to public inspection at a subsequent date preceding the expiry of the confidentiality period referred to in subsection 10(2) of the Act, that subsequent date.*

The request for withdrawal must therefore be made within 16 months of the filing date of the priority application or at a later date if the technical preparations to open the application to public inspection can be stopped. If the request for withdrawal of priority is made after the 18-month period beginning at the filing date of the priority document but prior to the 18-month period beginning at the filing date of the pending application, the pending application will have been laid open. For example, if the pending application is filed on the twelve-month anniversary of the filing date of the priority document, the applicant will generally have 4 months from the Canadian filing date to file a request for withdrawal of priority without prejudicing the confidentiality period.

7.07 Special topics

May 2014

Several additional considerations pertaining to valid priority rights but which are not explicitly addressed by the *Patent Act* and *Rules* should be noted.

7.07.01 Types of recognised priority documents

The Office recognises Paris Convention priority based on petty patent applications, applications for inventors' certificates[xi], and utility models filed in foreign countries[xii], as these are considered forms of patent applications. No priority rights for a patent application may be based on an application for an industrial design registration, design patents or their equivalent. In accordance with Article 4 of the Paris Convention, priority rights may not be based on the content of an application for an industrial design.

7.07.02 Same subject-matter in multiple priority documents

As detailed in section 7.03.01, any application filed more than one year before the filing date of a Canadian application may not form the basis of priority for the Canadian application.

Where a first application has been filed more than twelve months before the filing date of a Canadian application and a second application having the same subject-matter is filed within the 12-month period before the filing date of the Canadian application, priority cannot be based on the second application, except for subject-matter exclusive to the second application. In practice an examiner would not be expected to search for such documents but may come across them during a typical prior art search.

An exception to this bar is found in subsection 28.4(5) of the *Patent Act* which provides relief where the first application, filed more than one year before the Canadian filing date, has never been open to public inspection and will never publish.

If the first application has never been open to public inspection and is considered withdrawn, abandoned or refused by the granting authority, an inventor may be entitled to full priority rights based upon the subsequently filed second application or, where no previously filed applications remain, the claim date of the pending application will be the date the application is filed in Canada.

7.07.03 U.S. continuation and continuation-in-part applications

Under some conditions, priority may be based on continuation or continuation-in-part applications before the United States Patent and Trademark Office. A United States continuation application is an application which has the same specification of an earlier application but contains claims directed to either different subject-matter, i.e., a different invention than claimed in the earlier application or claims a different embodiment of the earlier claimed invention. No new matter is disclosed or claimed. A continuation-in-part application discloses and claims additional subject-matter over the earlier application.

If a Canadian application is filed within one year of a continuation-in-part application, this continuation-in-part application may serve as a priority document for any new matter not disclosed in the original U.S. application from which the continuation-in-part application extends.

Where a Canadian application is filed more than twelve months after the filing date of the original U.S. application, but within twelve months after the continuation-in-part, the applicant is not entitled to priority on subject-matter common to the two U.S. applications, except in circumstances as described below. If both the original and the continuation-in-part applications are filed within the 12-month period preceding the filing of the Canadian application, priority may be based on both the original application and on the new matter in the continuation-in-part.

Where priority is necessary to support a claim date in the prosecution of a Canadian application claiming priority from a U.S. continuation-in-part application only, it is necessary to identify the matter derived from the original U.S. application to determine the priority rights of the applicant. Because a U.S. continuation-in-part application does not identify the new matter added to the original U.S. application, the applicant must submit certified copies of both the original and continuation-in-part applications whenever required to do so by the Office.

Example:

An application is filed on March 1, 2009. In the Petition, the applicant requests priority from a US continuation application filed in the United States on March 2, 2008. The US continuation application is a continuation of a prior US application (the "original US application") filed before the USPTO on February 1, 2008. In the Petition, the applicant provides the application number, country code and filing date of the US continuation application and requests priority from this application.

Analysis:

The Canadian application will not be granted the priority date of the continuation application as the subject matter of the Canadian application was disclosed on February 1, 2008 in the original US application, which is more than twelve months before the date the application was filed in Canada. Note: If the second US application was a continuation-in-part application, the Canadian application would receive the priority from the filing date of the continuation-in-part only for the subject-matter disclosed uniquely therein (see also section 7.05).

Endnotes for chapter 7

i *Pfizer Canada v. Ratiopharm Inc.* 2010 FC 612 at paragraph 84, referring to *Apotex Inc. v. Merck & Co.* 2006 FCA 323, [2007] 3 F.C.R. 588 at paragraph 55.

ii "Regularly filed application" means any application which bears as its *filing date* the date on which it is received by the Office or an application filed in the Office at the national stage of an international application.

iii. Bodenhausen, G.H.C. *Guide to the Application of the Paris Convention for the Protection of Intellectual Property*. BIRPI, 1969. pp 37-38

iv. See Article 3 of the Paris Convention.

v Restoration of priority is addressed by Rule 26bis.3 of the PCT

vi. *Bristol-Myers Squibb Co. v. Canada (Commissioner of Patents)* 82 C.P.R. (3d) 192 affirming 77 C.P.R. (3d) 300 at paragraphs 28-30.

vii. Other recognised intergovernmental authorities include the Eurasian Patent Organization (EAPO) and the Gulf Cooperation Council Patent Office (GCCPO).

viii. See Article 11(4) of the PCT.

ix. The European Patent Office (EPO) grants patents enforceable in any Contracting State of the European Patent Convention (EPC) [see Article 2(2) of the EPC] unless the applicant for the European patent has withdrawn a Contracting State from designation [see Article 79(3) of the EPC]; a granted patent must, however, be validated in each Contracting State.

x. Subsection 90(1) of the *Patent Rules* refers to applicant and application; the patentee ceases to be an applicant for the purposes of subsection 28.4(3) of the *Patent Act* on the date the application issues to a patent and is therefore not entitled to withdraw priority from the patent.

xi. The term inventors' certificate replaces the formerly used authors' certificate but has the same effect. The change was made in the Paris Convention to avoid confusion with copyright authorship.

xii. See Article 4(I)(2) of the Paris Convention.

Chapter 8
Abstracts

8.01 Abstracts

June 2015

Subsection 27(2) of the *Patent Act* provides the authority for the requirements of a patent application. Pursuant to section 79 of the *Patent Rules* an application shall contain an abstract; although, an abstract is not a requirement for obtaining a filing date. An application other than a PCT national phase application, however, must contain an abstract in order to be complete (paragraph 94(2)(*b*)of the *Patent Rules*).

The abstract must be in English or French and in the same language as the rest of the application (subsection 71(3) of the *Patent Rules*). At grant the Office translates the abstract into the other official language to better enable searching in both official languages.

Section 79 of the *Patent Rules* sets forth the required form and content of the abstract and requires that the abstract:

- contain a concise summary of the matter contained in the application and, where applicable, the chemical formula that, among all the formulae included in the application, best characterizes the invention;
- specify the technical field to which the invention relates;
- be drafted in a way that allows the clear understanding of the technical problem, the gist of the solution of that problem through the invention, and the principal use or uses of the invention;
- be so drafted that it can efficiently serve as a scanning tool for purposes of searching in the particular art; and
- not contain more than 150 words.

Section 72 of the *Patent Rules* specifies that the abstract shall commence on a new page separate from the description, the drawings and the claims. For clarity, it should have a separate heading, such as, “Abstract of the Specification”. Since the abstract will be used as a search tool, the text should avoid patent jargon so that it may be readily understood by technicians and scientists and other persons who are interested in obtaining information about laid open patent applications and issued patents. It should provide a means for quickly determining the subject-matter of the specification so that the reader can decide whether a more detailed review of the document is warranted. The abstract should not refer to purported merits or speculative applications of the invention, and should not compare the invention with the prior art.

The abstract shall not contain drawings, however it may contain chemical or mathematical formulae or the like (Section 74 of the *Patent Rules*).

8.02 Reference characters in abstracts

September 2014

Each main technical feature mentioned in the abstract and illustrated by a drawing in the application may be followed by a reference character referred to in a drawing, placed between parentheses (subsection 79(7) of the *Patent Rules*). In the field of biotechnology, the identifier of a sequence listing, such as "SEQ ID NO:1" may be used in the abstract to refer to the sequence listing.

8.03 Examination of abstracts

September 2014

Abstracts are subject to examination in respect to their conformance with section 79 of the *Patent Rules*. In addition to setting forth the form and content of the abstract, subsection 79(1) of the *Patent Rules* states that the abstract "cannot be taken into account for the purpose of interpreting the scope of protection sought or obtained."

Following an amendment to the specification and drawings, the abstract cannot form the basis of support for subject-matter that was not present or reasonably inferred from the specification and drawings as originally filed.

8.04 Examples of abstracts

September 2014

The following examples illustrate what are considered to be suitable abstracts.

(a) A heart valve with an annular valve body defining an orifice and having a plurality of struts forming a pair of cages on opposite sides of the orifice. A spherical closure member is captively held within the cages and moved by blood flow between open and closed positions in check valve fashion. A slight leak or backflow is provided in the closed position by making the orifice slightly larger than the closure member. Blood flow is maximized in the open position of the valve by providing a convex profile on the orifice-defining surfaces of the body. An annular rib is formed in a channel around the periphery of the valve body to anchor a suture ring used to secure the valve within the heart.

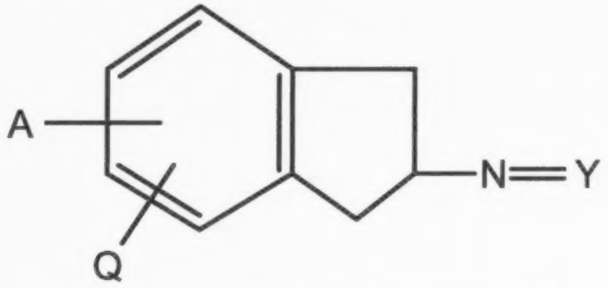
(b) A method comprising the use of heat to seal overlapping closure panels (1) of a folding box (2) made from paperboard having an extremely thin coating of moisture-proofing thermo-plastic material (3) on opposite surfaces (4). Heated air (6) is directed at the surfaces to be bonded (5), the temperature of the air at the point of impact on the surfaces (5) being above the char point of the board. The boxes (2) are moved so quickly through the air stream (6) that the coating (3) on the side of the panels (1) not directly exposed to the hot air (6) remains substantially non-tacky. A bond (7) is formed almost immediately after heating. Under such conditions the heat applied to soften the thermo-plastic coating (3) is dissipated after completion of the bond (7) by absorption into the board itself, which acts as a heat sink, without the need for cooling devices.

(c) Amides are produced by reacting an ester of a carboxylic acid with an amine, using as catalyst an alkoxide of an alkali metal. The ester is first heated to at least 75°C under a pressure of no more than 500 mm of mercury to remove moisture and acid gases which prevent the reaction, and then converted to an amide without further heating.

(d) Process for the production of semiconductor devices, wherein a silicon oxide film is formed on a surface of a semiconductor substrate, followed by deposition of a layer of lead on the film. This combination is then heated at 500-700°C for at least 10 minutes in an oxidizing atmosphere, whereby a passivating film forms, consisting essentially of silicon oxide and lead oxide. The temperatures employed are substantially lower than those conventionally used, and prevent deterioration of the device.

(e) Wool is heated at 50-65°C for less than 15 minutes in an aqueous dispersion of 0.1-2.0 percent calcium hydroxide, washed, and then acidified to render it receptive to dyestuffs without adversely affecting the physical properties of the wool.

(f) Compounds of the formula:



wherein A and Q are hydrogen or alkoxy groups and Y means an alkylene group with 4 to 7 carbon atoms, are useful as plant desiccants.

(g) Method by which a token-passing local-area network having from 2 to 2^n modules is initialized, where n is an integer greater than zero. When connected into the network and energized, each module determines if the network is initialized and, if not, which module is to do so. Each module has a unique n bit network address. The module with the smallest network address energized before the network is initialized is identified and begins the process of initialization by transmitting tokens addressed sequentially to network addresses beginning with the next higher address than its own until a token so transmitted is accepted by an addresses module or until a token has been addressed to all network addresses other than that of the initiating module. After tokens are transmitted to all possible network addresses other than that of the initiating module, the initiating module generates a fault signal to indicate its status.

Chapter 9
The Description

9.01 **Scope of this chapter** – December 2010

The description, together with the claims, form the specification of an application.[1] Although the claims play a prominent role in the patent system, in that they define the scope of the exclusive privilege conferred by a patent, a proper description is fundamental to a valid patent. As was noted by the Supreme Court, "[d]isclosure is the quid pro quo for valuable proprietary rights to exclusivity which are entirely the statutory creature of the *Patent Act*".[2]

The present chapter discusses the various requirements for proper disclosure under section 27(3) of the *Patent Act* as well as the various requirements as to the form and content of a description under the *Patent Rules*.

9.02 **General requirements of disclosure** – December 2010

The description must provide a clear and complete disclosure of the invention such that the person skilled in the art:

(1) can unambiguously identify what has been invented; and
(2) is enabled to practice this invention.[3]

In Consolboard Inc. v. Macmillan Bloedel (Saskatchewan) Ltd., Dickson J. noted that "the inventor must, in return for the grant of a patent, give to the public an adequate description of the invention with sufficiently complete and accurate details as will enable a workman, skilled in the art to which the invention relates, to construct or use that invention when the period of the monopoly has expired".[4] The description must be able to answer the questions "What is your invention?: How does it work?"[5] such that "when the period of the monopoly has expired the public will be able, having only the specification, to make the same successful use of the invention as the inventor could at the time of his application".[6]

It is beyond doubt that the "public" referred to in the foregoing quote takes the form of the person skilled in the art.

9.02.01 **Proper disclosure**

The statutory requirements of proper disclosure are set out in subsection 27(3) of the *Patent Act*, which requires that:

> The specification of an invention must
>
> (a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;
>
> (b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it;
>
> (c) in the case of a machine, explain the principle of the machine and the best mode in which the inventor has contemplated the application of that principle; and
>
> (d) in the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions.

Thorson P. summarized the foregoing requirements in Minerals Separation North American Corp. v. Noranda Mines, Ltd.,[7] noting that

> [t]he description must be correct; this means that it must be both clear and accurate. It must be free from avoidable obscurity or ambiguity and must be as simple and distinct as the difficulty of description permits. It must not contain erroneous or misleading statements calculated to deceive or mislead the persons to whom the specification is addressed and render it difficult for them without trial and experiment to comprehend in what manner the invention is to be performed. It must not, for example, direct the use of alternative methods of putting it into effect if only one is practicable, even if persons skilled in the art would be likely to choose the practicable method. The description of the invention must also be full; this means that its ambit must be defined, for nothing that has not been described may be validly claimed. The description must also give all information that is necessary for successful operation or use of the invention, without leaving such result to the chance of successful experiment, and if warnings are required in order to avert failure such warnings must be given. Moreover, the inventor must act *uberrima fide* and give all information known to him that will enable the invention to be carried out to its best effect as contemplated by him.[8]

The foregoing touches on both aspects of a sufficient disclosure: that it set out in clear and precise terms what the invention is (i.e. a correct and full description), and that it provide sufficient instructions to the person skilled in the art so that this person is enabled to reproduce and successfully operate the claimed invention.

9.02.02 Addressee is the person skilled in the art

The specification of an invention is directed to a person skilled in the art or science to which it pertains, or with which it is most closely connected.[9] Whether or not a description is sufficient depends on the interpretation it would be given by the person skilled in the art, who must interpret it with a mind willing to understand[10] and desirous of success.[11]

The person skilled in the art is competent, and represents an average, logical but unimaginative worker in the field.[12] This person is neither a dull-witted incompetent nor a creative, intuitive expert,[13] albeit that in a highly technical field the person skilled in the art may be presumed to have expert-level knowledge and skills.[14] Furthermore, the person skilled in the art is reasonably diligent in keeping up with advances in the field or fields of relevance to the invention,[15] and has the advantage of being multilingual and thereby being able to comprehend prior art in any language.[16]

In addition, the person skilled in the art need not be an actual individual; they are a fictitious construct and can represent a team of individuals whose conjoint knowledge is relevant to the invention in suit.[17]

In order to properly assess whether a correct and full description of the invention has been provided, it is necessary to identify the person skilled in the art to which the application is directed.

In accordance with paragraph 80(1)(b) and 80(1)(d) of the *Patent Rules*, the description must indicate the technical field of the invention and must allow an understanding of the technical problem being addressed and the solution to that problem through the invention.[18] The person skilled in the art will be competent in the field or fields of relevance to the invention.

A complexity arising from the nature of the person skilled in the art is that, as a general rule, neither the inventors nor the examiner may be directly equated to this person. Examiners and inventors, for example, are not free of creativity and intuition. They may have knowledge that surpasses that expected of the person skilled in the art in a given field, but again may not be as skilled in other fields of the invention as this person. During examination, an examiner must attempt to interpret the application and the prior art using the appropriate knowledge that the person skilled in the art would have possessed at the relevant date [see 9.02.03]. This may be particularly challenging where knowledge in the field at the date of examination has significantly developed since the relevant date, and particularly where certain views held at the relevant date have subsequently been found to be incorrect.[19]

Where the precise nature of the person skilled in the art is relevant for resolving an issue during examination, the examiner will determine who this person is and will take due account of any representations made by the applicant on point.

9.02.03 Description supplemented by common knowledge

A description sufficient to allow the person skilled in the art to practice the invention with the same success as the inventor is said to be enabling. Since the person skilled in the art is the addressee of the description, it is not necessary for common knowledge to be comprehensively disclosed nor to teach to the person skilled in the art things that would be plainly obvious to them.[20]

The date at which the person skilled in the art brings their knowledge to bear on the application is the date on which the application came into their possession; that is to say, the publication date.[21]

Since the common general knowledge may develop between the filing date and the publication date, this theoretically means that a specification that was not enabling as filed could nevertheless, on the basis of more extensive common general knowledge, be enabling by the publication date. However, the invention must still be fully described as of the filing date, and the utility of the invention must have been established no later than at this date [see 9.04].

9.02.04 Misleading or erroneous statements

The person skilled in the art will read a description with a mind willing to understand and desirous of success. They will use their common general knowledge to supplement the description in order to successfully operate the invention, and will overlook obvious errors or omissions that can be readily corrected.[22]

Where, however, a description includes statements that direct the person skilled in the art to attempt to practice the invention in a manner contrary to their common general knowledge, the person skilled in the art will nevertheless follow these explicit instructions. Where the manner of operation so disclosed will in fact not work to achieve the promise of the invention, the description does not comply with subsection 27(3) of the *Patent Act*.[23]

[For guidance regarding misleading definitions in the description, see 9.05.03.]

9.02.05 *Addressee not to be presented with problems to solve*

The person skilled in the art can be called upon to perform routine experiments to ensure proper operation of an invention, but must be able to practice the full scope of the invention without undue burden or the need to exercise their inventive ingenuity.

If the person skilled in the art is called on to solve problems in such a manner that undue burden or an inventive step are required, the description is insufficient (and the attendant claims are unsupported).[24] The obligation of the patentee for proper disclosure in this sense was described in Rice v. Christiani & Nielsen as:

> [h]e must so draft his specification, that a person having a competent knowledge of the industry concerned [...] will be able readily to ascertain from it the relation the invention bears to the existing knowledge in the industry, and so that one should not be called upon to do experimental work in order to discover how the invention may be made operative. There must be an open exposition by the patentee of everything that is necessary for the easy and certain procurement of the commodity for which the patent was granted. The patentee is not to tell a man to make an experiment but to tell him how to do the thing.[25]

H.G. Fox later described the relationship between the specification and the person skilled in the art as follows:

> [t]he person to whom the specification is addressed is presumed to possess all the existing knowledge common to the art to which the invention relates; this knowledge he must bring to bear in interpreting the specification. But he is not required to exercise or to be possessed of more, and, if the specification contains something that necessitates the working out of a problem, the patent cannot be supported.
>
> Where a specification describes an invention sufficiently clearly to enable a reasonably skilled workman to make use of it, even though some experiments are necessary, the patent will be good so long as those experiments do not require any exercise of the inventive faculty.[26]

In certain arts, it is common to describe an invention as relying on materials having certain required properties (a metal with a certain ductility; an insulator with a certain dielectric value, a molecule with a certain dipole moment), rather than by naming the materials explicitly. This is permissible as long as identifying those materials that have the required property does not require undue burden or inventive effort.

Requiring the absence of inventive effort implies that the solution to the problem being addressed must be readily apparent to the person skilled in the art (i.e. obvious). Solving a problem with a readily apparent solution is routine, and a description that requires the solving of such a problem could nevertheless be considered to be sufficient. The Courts have noted that it can be considered uninventive to engage in "routine testing to determine characteristics of known compounds, not undertaken for the purpose of 'searching for something novel', but rather for the purpose of verifying the actual attributes of already known compounds".[27]

While verifying the predicted or predictable properties of known compounds may therefore be considered to be routine,[28] "verification" means "confirmation" and determining the unexpected and unpredictable properties of new compounds is consequently not "verification".[29]

This reasoning can be extended to disciplines other than the chemical arts by formulating the statement as: a certain amount of routine testing is permitted in order to identify suitable materials for operating an invention, presuming the person skilled in the art knows or has been taught the necessary properties, how to determine them, and broadly what existing materials are likely to possess them.

Examples:

1. An invention describes a particular type of flange for connecting a plumbing fixture to a pipe, wherein it is necessary to construct the flange using a metal whose ductility is within a certain range. Identifying this operative ductility range is the discovery underlying the invention. Several metals having the necessary ductility are identified, and general teachings are given as to what types of metals are likely to have the necessary property. Testing ductility is within the common general knowledge of the person skilled in the art, and is routine.

Claim:

> 1. A flexible flange for connecting a plumbing fixture to a pipe, said flange comprising a metal having ductility in the range x-y and [...]

Analysis: The claim is given breadth by defining the flange in terms of a metal having ductility in the defined range, rather than in terms of specific operative metals. Whether or not the claim as defined is enabled depends on whether it can be operated without placing undue burden on the person skilled in the art. This depends on whether the person skilled in the art can readily identify suitable metals. Given that the person skilled in the art can test a given metal to determine whether or not it has the necessary ductility, that for many metals this data is already available in published references, and that the description suggests which metals are likely to be suitable, there is no invention in identifying metals that have the necessary property. Verifying the properties of known metals is "routine", and the person skilled in the art has not improperly been presented with problems to solve.

2. An applicant asserts as their invention drug compositions having very uniform release profiles for the active ingredient. Certain embodiments are disclosed based on particular salts of protected cyclic amines, but the invention is claimed in terms of drug compositions having the beneficial release profile, and not in terms of drug compositions of the particular family of salts.

Claim:

1. A medicament having a release profile characterised by [description of the profile]

Analysis: Consider that the release profile achieved is an unexpected and very beneficial property of the specific salts disclosed. The description does not disclose what chemical properties of the salt led to the defined release profile, nor does it guide the person skilled in the art as to what other compounds may provide a similar result. In order to operate the full scope of the claim, the person skilled in the art would have to solve the problem of identifying all the other salts that would lead to the same release profile. Since the identity of these other salts (presuming some may exist) is unobvious, an inventive step is associated with their identification. The description is insufficient to support the invention as broadly asserted.

9.02.06 Theory of the invention

As a general proposition, it is not necessary for the description to provide a theory as to why the invention operates as it does. The requirement is, simply, that the description teaches the person skilled in the art what the invention is and how to make it operate to provide the promised benefits.

Thus, as noted in Apotex v. Wellcome, "[i]t is generally not necessary for an inventor to provide a theory of why the invention works. Practical readers merely want to know that it does work and how to work it".[30]

This general proposition, however, has to be understood in an appropriate context. The Supreme Court thus added to the comment quoted above by stating, in respect of an invention relying on sound prediction, that "[i]n this sort of case, however, the sound prediction is to some extent the quid pro quo the applicant offers in exchange for the patent monopoly".[31] It can consequently be understood that if the utility of the invention is predicated on a sound prediction [see 12.08.04], and the line of reasoning depends on an understanding of the theory as to why the invention works, it may not be possible to properly express the line of reasoning unless this theory is disclosed.

9.03 Disclosing a solution to a practical problem – November 2017

As was noted by the Supreme Court in Apotex v. Wellcome, the granting of patents is "a method by which inventive solutions to practical problems are coaxed into the public domain".[32] Being a solution to a practical problem is what provides to the invention the practical utility necessary for patentability.

The description must put the person skilled in the art in a position to appreciate the nature of the problem being solved and the solution provided by the invention. For applications filed on or after October 1, 1996, paragraph 80(1)(d) of the *Patent Rules* explicitly provides that the description shall

> describe the invention in terms that allow the understanding of the technical problem, even if not expressly stated as such, and its solution.

In order to solve a practical problem, the solution must be in a form that can interact directly with the physical world and, hence, that will itself enable a person skilled in the art to obtain the intended result or benefit. That is, a patent is given for "the means by which a result is obtained ... rather than the result itself".[33] These means must consist of one or several elements, where an element in this sense could be either a physical object (a machine, article of manufacture or composition of matter) or a step leading to a physical effect in an art or process.

The group of elements that are made use of to obtain the benefit of the invention may, in combination, be referred to as the "practical form" of the invention (i.e. the form in which the invention may be practised). The practical form includes all the elements required to provide the utility of the invention.

In order for the description to properly disclose the practical form, it must supplement the common general knowledge of the person skilled in the art so as to put the invention into the hands of this person. Any novel element must therefore be fully described, as it was necessarily not previously known. Also, those elements (new or old) the person skilled in the art would not have known to use in combination to achieve the objects of the invention must be described, not only individually but in the appropriate combination.

For the description to disclose a patentable invention, it must describe (and the claims define) all the elements necessary to provide the useful result in a novel and inventive manner, and without which elements the solution would cease to be inventive.[34]

It is also necessary that the description provide such instructions as are necessary for the person skilled in the art to understand, where applicable, the interrelationship of the elements necessary to provide the practical form of the invention. The invention must be described so that, colloquially speaking, "the wheels will go round",[35] and must not require that the person skilled in the art perform modifications to the invention described in order to make it work.[36]

Although external documents may be referred to in the description, the invention must be described and enabled by the description alone as interpreted by the person skilled in the art in view of their common general knowledge. Specific prior art knowledge (e.g. information only available in one or a few documents, and which has not been shown to be commonly known and accepted) may be considered not to be "common general knowledge", and in such cases those specific teachings from the prior art necessary to describe or enable the invention must be included in the description in order to provide a full and complete disclosure.

It is not necessary to supplement a description of the foregoing with a description of those elements that would be self-evidently necessary to operate the invention, and whose use in the context of the invention as described would be obvious to the person skilled in the art.[37]

During prosecution, amendment to the claims may appear to alter the nature of the invention. Care must be taken to ensure that the inventor was, no later than the filing date, in possession of the invention asserted in the amended claims. Inventive ingenuity cannot post-date filing.[40] This is particularly relevant where features not identified in the original specification as being related to specific advantages are subsequently asserted as rendering the claims non-obvious over prior art disclosures. It is important to consider whether the description teaches that the elements in question are simply optional, or are essential elements of preferred embodiments. Where the inclusion of an element will lead to additional benefits over the invention as broadly disclosed, it should be viewed as an essential element of the "narrower invention" (the subject-matter in a claim of narrower scope).

9.04 This section has been intentionally left blank

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9.04.03 Combinations

A combination, in the sense the term is used herein, is an assemblage of parts (often of known parts) whose conjoint use leads to a result that is "different from the sum of the results of the elements" that make it up and "that is not attributable to any of the elements but flows from the combination itself and would not be possible without it".[55] Such a result may conveniently be termed a "unitary" result.[56]

A patentable combination has been explained in the following way:

> it is accepted as sound law that a mere placing side by side of old integers so that each performs its own proper function independently of any of the others is not a patentable combination, but that where the old integers when placed together have some working inter-relation producing a new or improved result then there is patentable subject matter in the idea of the working inter-relation brought about by the collocation of the integers.[57]

Where several parts are used together, each providing its expected result and the whole not leading to a unitary result, the assemblage is referred to as a "mere aggregation",[58] or simply as an "aggregation", to distinguish it from a true combination.

The utility of a combination is the unitary result it provides, and it is this result that must be established by demonstration or sound prediction.

Where, having described the structure of the combination, it would not be clear to the person skilled in the art what unitary result it achieves, a correct and full description of the result itself may be necessary to show that the combination is useful and inventive and to distinguish it from a mere aggregation.

9.05 **Special topics** – December 2010

The following sections set out practice in respect of certain specific topics which give rise to particular considerations with respect to proper disclosure.

9.05.01 Functional limitations

In certain cases, applicants may wish to describe or define an invention using functional language. The use of functional language, whether in a claim or in the description, is not *per se* objectionable. Such language, however, is generally used to provide breadth and must be carefully considered from the perspective of proper support.

Functional limitations must always be considered from the perspective of the person skilled in the art, with the question to be asked being: "can the person skilled in the art practice, in view of the description, the full breadth of the claimed invention without recourse to undue experimentation or inventive ingenuity?" [see 9.02.05]. If the means to effect the defined function are common general knowledge, the functional limitation is unlikely to be objectionable. Where few or only one means is known to effect the function, however, broad functional language would direct the claimed invention to be practised in ways that have not been fully described or enabled and consequently would be objectionable.

Typically, the inquiry into the appropriateness of functional language is driven by the language of the claims. Where an invention is defined in terms of an overly broad functional limitation, the claim seeks to monopolize speculative embodiments that the inventors have not adequately described. The corollary is that the description is not sufficient to support the invention as claimed.

To paraphrase Free World Trust v. Électro Santé Inc., it is not legitimate to invent a particular composition that grows hair on bald men and thereafter claim all compositions that grow hair on bald men.[59]

Thus, a claim to "a composition comprising a hair-growth activating compound in a pharmaceutically acceptable carrier", where only compound X is known to provide the function, would be too broad. The limitation "hair-growth activating" is a functional limitation to the scope of the compounds found in the composition, but does not serve to make the scope of the claim clear to the person skilled in the art. Identifying all the compounds that would have this activity would require extensive inventive experimentation amounting to invention [see 9.02.05]. The description, therefore, is not sufficient to describe and enable the invention asserted in the claim, and is objectionable under subsection 27(3) of the *Patent Act*.

In contrast, if it had been discovered that the combination of a particular drug with any non-steroidal anti-inflammatory (NSAID) compound led to unexpected advantages, functionally limiting the scope of the second component of the composition by the limitation "NSAID" would not be problematic. The scope of the term "NSAID" (or "NSAID compound") would be immediately apparent to the person skilled in the art.

Similarly, in a mechanical invention that relies on a "cutting means", a number of different cutting means would be known to the person skilled in the art. Where it would be readily apparent which would be suitable for operating the claimed invention, the limitation "cutting means" would not improperly broaden the claim. The identification and selection of appropriate cutting means would not require undue effort or further invention in such a circumstance.

9.05.02 Disclosure of biotechnological inventions

Specific disclosure requirements exist for some inventions in the fields of biotechnology. In brief, it may be necessary for a sequence listing of a nucleotide or amino acid sequence to be included with the description or for a deposit of biological material to be made with an International Depository Authority in order for the description of a biotechnology invention to be considered to be sufficient.

Details on the requirements for providing sequence listings or deposits of biological material are provided in subsection 17.05.07 and 17.06, respectively, of this manual.

9.05.03 The applicant as their own lexicographer

It has long been understood that the language of the claims is to be construed in view of the specification as a whole, and that the applicant can serve as their own lexicographer.

> Their Lordships do not doubt that it is possible for a patentee to make his own dictionary in this way. If he has put something in the earlier part of the specification which plainly tells the reader that for the purpose of the specification he is using a particular word with a meaning which he sets out, then the reader knows that when he comes to the claims he must read that word as having that meaning. But this is an awkward method of drafting and is very undesirable where a simpler method could easily be adopted and it is in all cases incumbent on a patentee who chooses to adopt this method to make his intention plain to those who read the specification.[60]

During examination, the language of the claims is interpreted by giving each term its plain and usual meaning in the art to which the invention pertains, unless it is clear from the description that a term in the claims is to be given a different meaning.

In the context of proper disclosure, it is to be noted that where an applicant, in attempting to act as their own lexicographer, creates a definition for a term that is contrary to the usual meaning ascribed to that term in the art, that is liable to cause confusion or ambiguity, or that is unnecessary in that other plain language could as easily provide the same information, the definition is objectionable. Recall in this context the requirement discussed in 9.02.01 that "[t]he description must be correct; this means that it must be both clear and accurate. It must be free from avoidable obscurity or ambiguity and must be as simple and distinct as the difficulty of description permits".

For example, where the description teaches that, for the purposes of the invention, the symbol P (phosphorus) designates nitrogen (elemental symbol N), this definition is only liable to cause confusion and is objectionable under subsection 27(3) of the *Patent Act*. The symbol is recognized in chemistry as designating phosphorus, and could readily be replaced by the appropriate symbol, N, to designate nitrogen.

In contrast, a definition is generally acceptable if, for the purposes of expediency and without sacrificing clarity, it narrows the scope of a term that would otherwise be attributed a broader meaning in the art. In a given case, it might be acceptable to define, for example, that the term "ethylene polymer" means "a non-crosslinked polymer comprising at least 80 mol% ethylene, with up to 20% $C_{3\text{-}8}$ alkene comonomer". Providing the longer definition at multiple instances would be unnecessarily cumbersome, and the definition provided unambiguously restricts the broader term.

9.05.04 Disclosure of trade-marked products

An invention may be operated by way of trade-marked products. Simply naming a trade-marked product is not, however, equivalent to describing the composition of that product.

Further, simply knowing what components are included in a trade-marked product does not identify which of those components is an essential element of the invention (i.e. which component or components are necessary to fulfill the trade-marked product's role in the invention). Thus, even though a person skilled in the art may, depending on the state of the art, be able to reverse engineer a trade-marked product and identify its components, this will not by necessity put them in possession of the invention.

Therefore, where an invention is described only in terms of a trade-marked product, the question of proper support must be carefully considered. If it is not clear which component of the product is responsible for the product's role in the invention, the invention cannot be operated other than by the trade-marked product itself.

If the composition of the trade-marked product is not known, and the product is not commercially available, the invention is not enabled.

Where an invention is described in terms of specific components (e.g. chemical compounds), but is supported by examples that rely on trade-marked products of undisclosed composition, no presumption exists that the examples embody the invention described. The applicant must establish that they were aware of the composition of the trade-marked product no later than at the filing date.

Where the composition of a trade-marked product did not form part of the prior art as of the filing date, its composition cannot subsequently be added to the application [see 9.08].

[For requirements regarding the identification of trade-marks, see 9.07.03.]

9.05.05 Description by reference to the claims

The invention must be "correctly and fully" described in the description, which according to section 2 of the Patent Rules is "that part of the specification other than the claims". Furthermore, in accordance with section 84 of the Patent Rules, the claims shall be fully supported by the description.

It is consequently improper for the description to state the nature of the invention by reference to the claims. Such statements suggest that the description does not "correctly and fully" disclose the invention and does not comply with subsection 27(3) of the *Patent Act*.

Therefore, where the description teaches in some fashion that the invention is "according to the claims", the statement must be removed or replaced by an explicit description of the invention.

By way of example, statements such as "the problem of premature ignition in the combustion chamber is overcome through the method of claim 1" or "the compositions as instantly claimed exhibit superior insecticidal properties" fail to set forth explicitly what the invention in question is, but suggest instead that the invention is whatever might be claimed at any given moment in time.

Note that amending the description to include the language of the claims originally filed is necessarily compliant with subsection 38.2(2) of the *Patent Act*.

9.05.06 Statements expanding the scope of the claims

This subsection has been deleted.

9.05.07 References to foreign practice or law

Where an application includes a statement whose correctness is dependent on foreign patent prosecution practices or laws, such a statement may be inaccurate or liable to cause confusion in the context of Canadian law. Where this is the case, the statement must be removed. The statements may be viewed as being "incorrect", and therefore a defect under subsection 27(3) of the *Patent Act* [see 9.09].

An indication that the application is a continuation-in-part or a divisional of a foreign patent document, for example, is not correct in the context of the Canadian Patent Act and must be removed.

A statement regarding the rights of foreign governments to the invention may also be misleading, and should be removed if it is inaccurate.

9.06 Form of the description – December 2010

The form a description should take is set out in section 80 of the *Patent Rules*.[62] Thus,

> (1) The description shall
>
> > (a) state the title of the invention, which shall be short and precise and shall not include any trade-mark, coined word or personal name;

(b) specify the technical field to which the invention relates;

(c) describe the background art that, as far as is known to the applicant, can be regarded as important for the understanding, searching and examination of the invention;

(d) describe the invention in terms that allow the understanding of the technical problem, even if not expressly stated as such, and its solution;

(e) briefly describe the figures in the drawings, if any;

(f) set forth at least one mode contemplated by the inventor for carrying out the invention in terms of examples, where appropriate, and with reference to the drawings, if any; and

(g) contain a sequence listing where required by subsection 111(1).

(2) The description shall be presented in the manner and order specified in subsection (1) unless, because of the nature of the invention, a different manner or a different order would afford a better understanding or a more economical presentation.

The provisions of subsection 80(2) of the *Patent Rules* would allow, for example, that drawings associated with the prior art be described with the background art, prior to the brief description of the figures in any remaining drawings.

The title of the invention should be descriptive of the invention in suit, and not merely of the field to which the invention pertains. A title such as "flame-retardant rigid polyurethane foam" is acceptable, whereas "foam" is not.[63]

In accordance with paragraph 80(1)(a) of the *Patent Rules*, the Office considers the title provided in the description to be the correct title of the invention. Where, for any reason, the title ascribed to the invention in the Office's electronic database differs from the title provided in the description, the electronic database will be updated at the time of grant to reflect the title set out in the description.[64]

Disagreement between the title in the description and the title in the Office's electronic database is not a defect in the application. An examiner may note the existence of such a disagreement, in order to apprise the applicant of the situation and provide them with an opportunity to address the matter. Such a disagreement may also be brought to the applicant's attention subsequent to allowance, by way of an Office letter.

Paragraph 80(1)(c) of the *Patent Rules* requires that the applicant describe the background art that, as far as is known to them, is important for the understanding, searching and examination of the invention. Where relevant background art is identified during prosecution, an applicant may, within the limitations imposed by section 38.2 of the *Patent Act* [see 9.08], introduce to the description references to and descriptions of the contents of prior art documents where these are clearly admitted to be prior art with respect to the application. Examiners should, in general, not raise an objection simply because the description has not been amended to identify background art brought to the applicant's attention subsequent to filing.

Paragraph 80(1)(f) of the *Patent Rules* provides that, "where appropriate", the applicant must set forth in terms of examples, at least one mode contemplated by the inventor for carrying out the invention. The use of the wording "where appropriate" in this rule reflects that an exemplary basis may or may not be necessary depending on the case at hand. The language "where appropriate" does not merely mean "if the applicant deems it appropriate", and does not provide any exception to the disclosure requirements of subsection 27(3) of the *Patent Act*.

It is not necessary for the description to present the information required by section 80 of the *Patent Rules* in sections bearing headings corresponding to the paragraphs of subsection 80(1), although an applicant may choose to do so for the sake of clarity.

Headings such as "Summary of the Invention", "Detailed Description of the Invention" and "Detailed Description of the Preferred Embodiments" are permitted in Canadian practice. It is worth noting, however, that where a heading such as "Detailed Description of the Preferred Embodiments" is used, support for claims broader than these embodiments must be found in other parts of the description which must satisfy the requirements of subsection 27(3) of the *Patent Act*, including enablement and support for any sound prediction, in respect of the invention as broadly claimed.

9.07 Formalities requirements of the description – December 2010

The description is subject to many formalities requirements dealing with various aspects of its contents and presentation. These are summarized in the following sections.

9.07.01 Pages of the description

In accordance with subsection 73(1) of the *Patent Rules* the description must be on consecutively numbered pages,[65] and in accordance with section 72 of the *Patent Rules* no page of the description may contain anything belonging to another part of the application.[66]

9.07.02 Drawings, graphics and tables

In accordance with section 74 of the *Patent Rules*, the description shall not contain drawings[67] but may contain chemical or mathematical formulae or the like.[68] For greater clarity, a chemical formula may be presented in the description in graphical form (i.e. as a structure).[69] The description may also contain information presented in tables. In accordance with subsection 75(2) of the *Patent Rules*, any formula or table may, where it aids presentation, be presented sideways (i.e. in landscape format) with the top of the formula or table at the left side of the sheet.[70] Otherwise, subsection 75(1) of the *Patent Rules* provides that pages of the description must be used upright (i.e. in portrait format).[71]

It can be inferred from section 37 of the *Patent Act* that a drawing is an illustration of the invention. Schematics that illustrate a process, such as flow-charts, are generally considered to be drawings.

Graphical representations of data, such as graphs, histograms, pie charts, and spectra, are not necessarily to be viewed as "illustrations of the invention", and therefore may be included in the description. Where a graphical representation of data is provided as a drawing, it must comply with all the requirements of section 82 of the *Patent Rules*.

Tabulated data generally cannot be considered a "drawing", and typically should be presented in the description.

Where the application contains drawings, subsection 82(9) of the *Patent Rules* requires that any reference characters appearing on any figures in the drawings, and only these reference characters, be mentioned in the description.[72] Further, where features are identified by reference characters, subsection 82(10) of the *Patent Rules* requires that the same reference characters must be used throughout the description to refer to those features, and may not be used to refer to any other features.[73]

9.07.03 Identification of trade-marks

In accordance with section 76 of the *Patent Rules*, any trade-mark mentioned in the application shall be identified as such.[74] The Office requires that each trade-mark be identified in an appropriate manner at least once, preferably at its first appearance.

Use of the words "trade-mark" in parentheses, of the designation "™", or of an indicator such as an asterisk (*) linked to a footnote denoting that the asterisk designates a trade-mark are all examples of appropriate manners for identifying a trade-mark in an application.

9.07.04 Identification of documents

In accordance with section 81 of the *Patent Rules*, a document referred to in the description must be available to the public and be fully identified, and shall not be incorporated by reference.[75]

The Office considers a patent document to be properly identified when the country or office code is provided along with a number under which the published version of the document can be found. Thus, the number provided can be that given to a granted patent, or be either the application number or publication number of a published application.

WO 96/937212, US 5,410,288, and EP 1 004 793 are examples of patent documents properly identified by a publication or patent number.

PCT CA2006/001,285 and U.S.S.N. 11/421,399 are examples of application numbers which are acceptable if the identified application has been published.

PCT applications, and US applications filed after November 28, 2000, will generally be published unless the application has been withdrawn (or, in the case of US applications, abandoned) prior to the publication date. Under 35 U.S.C. 122, a US application may also be kept confidential (i.e. will not be published) if the applicant certifies that they will not file an application for the disclosed invention in any other country. Where a US application is relied on as a priority document, this provision does not apply. US provisional applications, applications for design patents, and applications in series 09 or earlier are not necessarily published and may not be referred to by their application numbers unless the document is available to the public.[76]

For non-patent documents, the requirement is that the document be sufficiently well identified to permit it to be obtained by an interested party.

For a journal article, textbook, or the like, the document should be identified by the names of the author and the publication, the year of publication, the volume and/or issue number(s) if applicable, and the page numbers of the article, number of the chapter or the like. Preferably, the title of an article or title of a chapter should be provided. Additional information, such as the name of the publisher, may be included. Where a unique document identifier such as an ISBN code is provided, this does not replace any of the foregoing requirements.

References to internet pages present a particular difficulty in that neither the URL nor the content of such pages is necessarily fixed. Examiners will object to the identification of a document by way of a URL where it is not clear that the URL refers to a reliable, publically available source that can reasonably be expected to ensure the information in question is of fixed content and will be more or less permanently retrievable.

9.08 **Amendments to the description** – December 2010

In accordance with subsection 38.2(1) of the *Patent Act*, the description is subject to amendment before grant. Under subsection 38.2(2) of the *Patent Act*, any such amendment may not introduce "matter not reasonably to be inferred from the specification or drawings as originally filed, except in so far as it is admitted in the specification that the matter is prior art with respect to the application" (for convenience, such matter may be referred to simply as "new matter").

Note that one amendment that is always permissible from the standpoint of "new matter" is the inclusion of the language of the originally filed claims in the description.

General guidance regarding the amendment of applications is provided in chapter 19 of the manual.

As regards the description, particular attention must be given to amendments that replace restrictive language with permissive language. Where an application teaches that the invention (as opposed to an embodiment of the invention) "must be" or "is" (or the like) operated in a certain way, amendment of this language to indicate that the invention "preferably" or "optionally" (or the like) is operated in that way enlarges the scope of the invention and may be seen as the addition of new matter.

Similarly, it is possible for the deletion of text to amount to the addition of new matter. If a passage in the description teaches that an invention is inoperative under certain conditions, an amendment to remove this guidance could be viewed as introducing new matter by expanding the scope of the operable invention.

Where a description included both permissive and restrictive language regarding a certain limitation, amending the description to make it self-consistent throughout will generally not be seen as the addition of new matter.

An invention requires an inventive step, and the presence of this inventive step must be evaluated in view of the specification as filed. Amendments that appear to introduce new aspects of "inventiveness" to the application introduce new matter.

Remembering that an invention is a solution to a practical problem, it can be understood that amendments that tend to transform the invention as originally disclosed into a new invention - that is to say, into a new solution to the same or a different problem - constitute the addition of new matter.

Such amendments shift the point of invention and have the effect of causing a different invention to be disclosed than that in the specification as originally filed.

The description may be amended to make reference to prior art documents. Where the amendment is merely to clarify the state of the art, this will generally not be considered to introduce new matter. Where, however, an amendment introduces information from a prior art document, these amendments may, depending on the circumstances, introduce new matter.

Where specific teachings in a prior art document are required in order to enable the invention to be operated, or in order to support a sound prediction of utility, and it would not have been clear to the person skilled in the art, as of the claim date, which teachings in the prior art document were necessary for this purpose, identifying or including the specific teachings constitutes the addition of new matter.

9.09 **Office actions on the description** – December 2010

Objections dealing with substantive issues of sufficiency are presented under subsection 27(3) of the *Patent Act*, or a specific paragraph of that subsection where this precision may be helpful in underlining the basis of the objection.

As is the case with objections under subsection 27(4) of the *Patent Act*, however, the defects being objected to under subsection 27(3) can range from significant issues of sufficiency to fairly minor defects of clarity. The presence of a subsection 27(3) objection is not by necessity an indication of any un-remediable defect relating to sufficiency.

Nevertheless, wherever a more specific authority exists on which to base the objection being made, this authority should be used in place of subsection 27(3) of the *Patent Act*. For example, if a reference character has been included in the drawings but is not mentioned in the description, this defect should be presented under subsection 82(9) of the *Patent Rules* rather than under subsection 27(3) of the *Patent Act*.

Objections to formatting or other minor problems are presented under authority of whichever section relates to the defect under consideration [see 9.07 and the related endnotes].

Non-compliance with the formatting requirements set out in sections 68, 69 and 70 of the *Patent Rules* [see section 5.03 of this manual] can be identified by an examiner in order to inform applicants of any defects and expedite advancing the application to allowance. It is not, however, required for an examiner to do so, since correction of these defects can also be requisitioned by examination support staff. It is noted that the Canadian requirements as to formatting are based on those required under the Patent Cooperation Treaty, and requisitioning compliance with the Canadian requirements is therefore permissible under Article 27, PCT.

Endnotes for chapter 9

1. See the definitions of "description" and "claims" in section 2 of the Patent Rules.

2. Apotex Inc. v. Wellcome Foundation Ltd. 2002 SCC 77 at paragraph 37

3. Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents) [(1989), 25 C.P.R. (3rd), 257 (S.C.C.)] at page 268; Apotex v. Wellcome (supra at 2) at paragraph 70; Electrolytic Zinc Process Co. v. French's Complex Ore Reduction Co. [1930] S.C.R. 462 at paragraph 22; Leithiser v. Pengo Hydra-Pull of Canada Ltd. [(1974), 17 C.P.R. (2nd), 110 (F.C.A.)] at pages 113-115; Lundbeck Canada Inc. v. Minister of Health 2009 FC 146 at paragraph 135; Pfizer Canada Inc. v. Novopharm Limited 2009 FC 638 at paragraph 105. See also Apotex Inc. v. Sanofi-Synthelabo Canada Inc. 2008 SCC 61, e.g. at paragraph 26, applying these requirements to prior disclosures being considered for the purposes of anticipation.

4. Consolboard Inc. v. Macmillan Bloedel (Saskatchewan) Ltd. [(1981), 56 C.P.R. (2nd), 145 (S.C.C.)] at pages 154-155, Dickson J. quoting H.G. Fox from his Canadian Law and Practice Relating to Letters Patent for Inventions [(1969), 4th Ed.]

5. Consolboard (supra at 4) at page 157

6. Minerals Separation North American Corp. v. Noranda Mines, Ltd. [(1947), 12 C.P.R. (1st), 102 (Ex.Ct.)] at page 111

7. Minerals Separation (supra at 6)

8. Minerals Separation (supra at 6) at pages 111-112, with these points being reasserted by Thurlow J. in Société des Usines Chimiques Rhone-Poulenc et al. v. Jules R. Gilbert Ltd. et al. [(1968), 55 C.P.R. (1st), 207 (S.C.C.)] at pages 225-226; Wandscheer et al. v. Sicard Limitée [(1947), 8 C.P.R. (1st), 35 (S.C.C.)] at pages 39-40.

9. This position has been adopted by the courts so often that it has become axiomatic. See, e.g., Whirlpool Corp. v. Camco Inc. 2000 SCC 67 at paragraph 53; Consolboard (supra at 4) at page 160

10. Free World Trust v. Électro Santé Inc. 2000 SCC 66 at paragraph 44, quoting H.G. Fox from his Canadian Law and Practice Relating to Letters Patent for Inventions [(1969), 4th Ed.] at page 184; Whirlpool (supra at 9) at paragraph 49, citing Lister v. Norton Brothers and Co. [(1986), 3 R.P.C. 199 (Ch.D.)] at page 203

11. Free World Trust (supra at 10) at paragraph 44

12. From Beloit Canada Ltd. v. Valmet Oy [(1986), 8 C.P.R. (3rd), 289 (F.C.A.)] at page 294 we know them to be a "paragon of deduction" and from Whirlpool (supra at 9 at paragraph 74) we know them to be "reasonably diligent in keeping up with advances in the field to which the patent relates". See also the comments on point in Janssen-Ortho Inc. v. Novopharm Limited 2006 FC 1234 at paragraph 113.

13. Bayer Aktiengesellschaft v. Apotex Inc. [(1995), 60 C.P.R. (3rd), 58 (On.Ct.G.D.)] at page 79

14. Servier Canada Inc. v. Apotex Inc. 2008 FC 825 at paragraph 99

15. Servier (supra at 14) at paragraph 254

16. Axcan Pharma Inc. v. Pharmascience Inc. 2006 FC 527 at paragraph 38

17. Bayer AG (supra at 13) at page 79; Johnson & Johnson Inc. v. Boston Scientific Ltd. 2008 FC 552 at paragraph 97; Lundbeck Canada Inc v. Minister of Health 2009 FC 146 at paragraph 36

18. In respect of applications filed on or after October 1, 1996.

19. The comments in GlaxoSmithKline Inc. v. Pharmascience Inc. 2008 FC 593 at paragraph 35, while they relate to expert witnesses at trial and not to examiners and inventors/applicants during examination, are illustrative.

20. see, e.g., Apotex v. Sanofi-Synthelabo (supra at 3) at paragraph 37; Burton Parsons Chemical Inc. v. Hewlett-Packard (Canada) Ltd. [(1976), 17 C.P.R. (2nd), 97 (S.C.C.)] at page 105

21. Pfizer v. Novopharm (supra at 3) at paragraph 108; Sanofi-Aventis Canada Inc. v. Apotex 2009 FC 676 at paragraph 233; Free World Trust (supra at 10) at paragraph 54. Note, however, that the Supreme Court in Free World Trust was addressing the date for claim construction rather than enablement.

22. Apotex v. Sanofi-Synthelabo (supra at 3) at paragraph 37. During examination, such obvious errors should be corrected whenever identified.

23. TRW Inc. v. Walbar of Canada Inc. [(1991), 39 C.P.R. (3rd), 176 (F.C.A.)] at page 197

24. Procter & Gamble Co. v. Bristol-Myers Canada Ltd. [(1978), 39 C.P.R. (2nd), 145 (F.C.T.D.)] at pages 159-160, aff'd [(1979), 42 C.P.R. (2nd), 33 (F.C.A.)]; see also

Apotex v. Sanofi-Synthelabo (supra at 3) at paragraphs 33-37

25. Rice v. Christiani & Nielsen [1929] Ex.C.R. 111 at paragraph 9, rev'd on other grounds

26. H.G. Fox, Canadian Law and Practice Relating to Letters Patent for Inventions [(1969), 4th Ed., Carswell (Toronto)] at page 171; the last sentence in the first paragraph was quoted with approval in Pioneer Hi-Bred (supra at 3) at page 270

27. Janssen-Ortho Inc. v. Novopharm Ltd. 2004 FC 1631 at paragraph 54; quoted in Bristol-Myers Squibb Canada Co. v. Novopharm Ltd. 2005 FC 1458 at paragraph 71, Aventis Pharma Inc. v. Apotex Inc. 2005 FC 1504 at paragraph 126. Note that in the foregoing cases the Courts were addressing the question of obviousness, and whether engaging in routine testing made the result of that testing unobvious. However, the link between the obviousness analysis and the evaluation of sufficiency is addressed in Sanofi-Aventis Canada Inc. v. Ratiopharm Inc. 2010 FC 230 at paragraphs 57-80. See also the comments in Pfizer Limited v. Ratiopharm 2010 FCA 204 at paragraphs 16 to 27.

28. Pfizer Canada Inc. v. Canada (Minister of Health) 2006 FCA 214 at paragraph 24

29. Janssen-Ortho Inc. v. Apotex Inc. 2008 FC 744 at paragraph 111; Pfizer v. Canada (supra at 28) at paragraphs 26 and 27

30. Apotex (supra at 2) at paragraph 70

31. Apotex (supra at 2) at paragraph 70

32. Apotex (supra at 2) at paragraph 37

33. Norac Systems International Inc. v. Prairie Systems & Equipment Ltd. 2002 FCT 337 at paragraph 16, rev'd in part on other grounds 2003 FCA 187

34. Dimplex North America Ltd. v. CFM Corp. 2006 FC 586 at paragraph 80, aff'd 2007 FCA 278; citing Norac Systems (supra at 33)

35. Fox (supra at 26) citing at pages 150-151 Mullard Radio Valve Company Ltd. v. Philco Radio and Television Corporation of Great Britain Ltd. [(1935), 52 R.P.C. 261] at page 287; quoted in Eli Lilly Canada Inc. v. Novopharm Ltd. 2007 FC 596 at paragraph 188 and in Consolboard Inc. v. Macmillan Bloedel (Saskatchewan) Ltd. [(1978), 39 C.P.R. (2nd), 191 F.C.T.D.)] at page 216

36. Norac Systems (supra at 33) at paragraph 41; Almecon Industries Ltd. v. Anchortek Ltd. 2001 FCT 1404 at paragraph 45, aff'd 2003 FCA 168, citing

Consolboard Inc. v. Macmillan Bloedel (Saskatchewan) Ltd. [(1978), 39 C.P.R. (2nd), 191 F.C.T.D.)] at page 216

37. Metalliflex Ltd. v. Rodi & Wienenberger Aktiengesellschaft [(1960), 35 C.P.R. (1st), 49 (S.C.C.)] at pages 53-54

38. Apotex (supra at 2) at paragraph 46

39. Pfizer v. Novopharm (supra at 3) at paragraphs 76 and 82, aff'd 2010 FCA 242 at paragraph 82

40. see, e.g., Novopharm Limited v. Janssen-Ortho Inc. 2007 FCA 217 at paragraph 26; Johnson & Johnson Inc. v. Boston Scientific Ltd. 2008 FC 552 at paragraphs 376-377; Pfizer Canada Inc. v. The Minister of Health 2008 FC 13 at paragraphs 99 and 118

41. Apotex (supra at 2) at paragraph 70

42. Eli Lilly Canada Inc. v. Apotex Inc. 2009 FCA 97 at paragraphs 10-18; Eli Lilly Canada Inc. v. Novopharm Limited 2009 FC 235 at paragraph 101; Servier (supra at 14) at paragraph 379

43. Eli Lilly Canada Inc. v. Apotex Inc. 2008 FC 142 at paragraphs 163-164; Eli Lilly v. Apotex (supra at 42) at paragraph 12

44. Eli Lilly v. Apotex (supra at 42) at paragraph 18; this requirement extends equally to any factual basis needed to support a sound prediction of an advantage possessed by a selection from a broader group, see Pfizer Canada Inc. v. Canada (Minister of Health) 2008 FC 500 at paragraph 97 and GlaxoSmithKline (supra at 19) at paragraph 71

45. Apotex (supra at 2) at paragraph 70; Pfizer Canada Inc. v. Canada (Minister of Health) 2007 FCA 209 at paragraph 152

46. Pfizer Canada Inc. v. Apotex Inc. 2007 FC 26 at paragraphs 66-70; aff'd 2007 FCA 195 - the Court concluded its observations on the patent in suit by noting that "[u]tility and sound prediction are questions of fact and must obviously be supported by evidence."

47. Servier Canada Inc. v. Apotex 2008 FC 825 at paragraph 379; Eli Lilly v. Apotex (supra at 42) at paragraph 18; Eli Lilly v. Novopharm (supra at 42) at paragraphs 101 and 107; Merck & Co. v. Apotex Inc. 2005 FC 755 at paragraphs 125-126

48. I.G. Farbenindustrie A.G.'s Patents [(1930), 47 R.P.C. 289] at pages 322-323; these criteria appear to have been endorsed in Canada at least as early as 1947 in Minerals Separation (supra at 6 at pages 163-164). They were endorsed by the Supreme Court in Apotex v. Sanofi-Synthelabo (supra at 3) at paragraph 10.

49. GlaxoSmithKline (supra at 19) at paragraph 70 and at paragraph 51 with reference to Dreyfus and Others Application [(1945), 62 R.P.C. 125 (H.L.)] at page 133; I.G. Farbenindustrie (supra at 48) at page 327

50. Pfizer Canada Inc. v. Canada 2006 FCA 214 at paragraph 4

51. Apotex v. Sanofi-Synthelabo (supra at 3) at paragraph 9; I.G. Farbenindustrie (supra at 48) at page 321

52. Pfizer Canada Inc. v. Ranbaxy Laboratories Limited 2008 FCA 108 at paragraph 59; Eli Lilly Canada Inc. v. Apotex Inc. 2007 FC 455 at paragraph 89

53. I.G. Farbenindustrie (supra at 48) at page 323

54. see, e.g., Eli Lilly Canada Inc. v. Novopharm Limited 2009 FC 235 at paragraph 100; Eli Lilly Canada Inc. v. Novopharm Ltd. (supra at 35) at paragraph 162; Ratiopharm Inc. v. Pfizer Limited 2009 FC 711 at paragraph 179; Pfizer Canada Inc. v. The Minister of Health (supra at 40) at paragraphs 115-116; note the similarity to the comments rendered in Pfizer v. Apotex (supra at 46) at paragraphs 66 and 69

55. The King v. American Optical Co. [(1950), 13 C.P.R. (1st), 87 (Ex.Ct.)] at page 98

56. The King v. American Optical (supra at 55)

57. Lester v. Commissioner of Patents [(1946), 6 C.P.R. (1st), 2 (Ex.Ct.)] citing at page 3 British Celanese Ltd. v. Courtaulds Ltd. [1935] 52 R.P.C. 171 at page 193

58. Domtar Ltd. v. MacMillan Bloedel Packaging Ltd. [(1977), 33 C.P.R. (2nd), 182 (F.C.T.D.)] at pages 189-190; Bergeon v. De Kermor Electric Heating Co. [1927] Ex. C.R. 181 at paragraphs 29 and 81; Schmuel Hershkovitz v. Tyco Safety Products Canada Ltd. 2009 FC 256 at paragraph 148; Free World Trust (supra at 10) at paragraph 27

59. Free World Trust (supra at 10) at paragraph 32

60. Minerals Separation North American Corp. v. Noranda Mines, Ltd. [(1952), 15 C.P.R. (1st), 133 (P.C.)] at pages 144-145

61. Free World Trust (supra at 10) at paragraph 31

62. Section 80 of the Patent Rules applies to applications filed after October 1, 1996. There is no equivalent to this rule for earlier-filed applications.

63. Note that, for applications filed prior to October 1, 1996 and October 1, 1989, respectively, the requirement that an invention have a title are governed by sections 134 and 170 of the Patent Rules.

64. This practice was first communicated in the practice notice Title of Invention [C.P.O.R. Vol. 137, No. 4, January 27, 2009].

65. This requirement is governed by subsection 135(4) of the Patent Rules for applications filed before October 1, 1996 and by subsection 171(4) of the Patent Rules for applications filed before October 1, 1989.

66. There is no such requirement in the Patent Rules governing applications filed prior to October 1, 1996.

67. This requirement is explicitly governed by subsection 74(1) of the Patent Rules for applications filed on or after October 1, 1996, by subsection 135(3) of the Patent Rules for applications filed before October 1, 1996 and by subsection 171(3) of the Patent Rules for applications filed before October 1, 1989.

68. The permissibility of chemical and mathematical formulae, and the like, is provided by subsection 74(2) of the Patent Rules for applications filed on or after October 1, 1996; for applications filed prior to October 1, 1996 this may only be implied by the lack of any proscription to formulae per se.

69. The permissibility of such presentation in applications filed on or after October 1, 1996 is implied from subsection 74(2) of the Patent Rules. Explicit permission for such presentation is provided by subsection 135(3) of the Patent Rules for applications filed before October 1, 1996 and by subsection 171(3) of the Patent Rules for applications filed before October 1, 1989.

70. This requirement is governed by subsection 135(2) of the Patent Rules for applications filed before October 1, 1996 and by subsection 171(2) of the Patent Rules for applications filed before October 1, 1989.

71. This requirement is governed by subsection 135(2) of the Patent Rules for applications filed before October 1, 1996 and by subsection 171(2) of the Patent Rules for applications filed before October 1, 1989.

72. No such explicit provision exists for applications filed prior to October 1, 1996.

73. This requirement is governed by paragraphs 141(1)(g) of the Patent Rules for applications filed before October 1, 1996 and by paragraph 177(1)(g) of the Patent Rules for applications filed before October 1, 1989.

74. This requirement is governed by section 140 of the Patent Rules for applications filed before October 1, 1996 and by section 176 of the Patent Rules for applications filed before October 1, 1989.

75. These requirements are governed by section 137 of the Patent Rules for applications filed before October 1, 1996 and by section 173 of the Patent Rules for applications filed before October 1, 1989.

76. Information regarding the publication of US patent documents is provided based on an interpretation of US practice as expressed in the USPTO's Manual of Patent Examining Procedure, 8th Ed. (August 2001) as revised July 2008. See, e.g., sections 101 and 103.

Chapter 10
Drawings

10.01 Drawings September 2015

Inventions which can be illustrated by means of drawings must be so illustrated in an application for a patent. The role of the drawings is to clarify the principles of the construction of a device rather than to provide particular details of dimensions or relative proportions. The drawings must clearly show all parts of the invention (subsection 37(1) of the *Patent Act*). Known devices may be illustrated by symbols which have a universally recognized conventional meaning provided that no further detail is essential for understanding the subject-matter of the invention. Where text matter in the drawings would give a better understanding of the drawings, a single word or a few words may be used. Blank "blocks" in schematic diagrams must be descriptively labelled. Figures in the drawings which illustrate the prior art should be labelled "PRIOR ART".

Each drawing must include reference characters corresponding with those in the description, and the Commissioner may require further drawings or dispense with any of them as the Commissioner sees fit (subsection 37(2) of the *Patent Act*).

Whenever drawings are provided in an application, they must conform to the provisions of sections 72 and 82 and subsections 69(2), 71(3), 74(1) and 75(2) of the *Patent Rules*. Subsection 80(2) of the *Patent Rules* permits reference to the drawings before the "Brief Description of the Drawings" when the reference is made in respect of prior art.

10.01.01 Amendments to drawings

Subsection 38.2(1) of the *Patent Act* states that the specification and any drawings furnished as part of an application may be amended before the patent is issued. Drawings may not be amended to add matter not reasonably to be inferred from the specification or drawings as originally filed, except in so far as it is admitted in the specification that the matter is prior art with respect to the application (subsection 38.2(3) of the *Patent Act*).

Detailed information on making amendments to patent applications can be found in Chapter 19 of this manual.

10.02 Photographs September 2015

In any case in which an invention does not admit of illustration by means of drawings but does admit of illustration by means of photographs, the applicant may, as part of the application, furnish photographs, or photocopies of photographs, that illustrate the invention (section 83 of the *Patent Rules*).

Chapter 11
Claims

11.01 Basic requirements March 1998

The claims must define distinctly and in explicit terms the subject matter of the invention for which protection is sought (section 27(4) of the *Patent Act*). Patentable claims must define novel subject matter. To be considered novel the whole of subject matter defined by a claim shall not form part of the state of the art. With respect to each claim in an application for patent in Canada the state of the art may be defined generally as everything disclosed in such a manner that it became available to the public in Canada or elsewhere before the **CLAIM DATE**. The **CLAIM DATE** of a claim in a Canadian patent application is the filing date of the application in Canada, unless, priority is claimed on an earlier filed application in Canada or elsewhere. In the latter case, the claim date is the filing date of the earliest application which supports the subject matter of the claim Sections 2 and 28.1 of the *Patent Act* and Chapter 15 for more detail. The claims should also specify in a positive manner all the elements, features, and critical aspects of the invention which are necessary to ensure the result as set forth in the description. Each claim (read with the introduction to the claims) must be restricted to a single sentence.

Claims may be drafted to contain the three following major parts:

1) preamble or introductory phrase
2) transitional phrase
3) body (or purview)

The preamble identifies the category of the invention and may state the purpose of the invention with regard to this category.

Examples:

A machine for waxing paper ...
A composition for fertilizing the soil ...

The transitional phrase joins the preamble to a recitation of the elements of the invention to be protected. It also indicates, in an abbreviated way, whether the recitation is left open or closed to additional elements.

Examples:

> which comprises, comprising, including, having ...
> consisting of, consisting essentially of ...

The body of the claim lists the main elements of the invention, such as, parts of a device, steps of a process or method, ingredients of a composition, or groups in the chemical formula of a compound.

Notwithstanding the above, the Patent Office will accept any form of claim that conforms to section 27(4) of the *Patent Act* and that sets forth an invention in distinct and explicit terms and otherwise conforms to the *Patent Act* and the *Patent Rules*.

For a consideration of claims with respect to the prior art (novelty and non-obviousness) see Chapter 15.

For consideration of claims with respect to utility, operability and non-patentable subject matter (section 2 of the *Patent Act*) see Chapter 16.

11.02 Principles of construction March 1998

Claims are the starting point for construing a patent as they define the invention and exclusive right sought. The relevant date for the analysis of a claim is the claim date (see Chapter 15). When construing a claim the essential elements must be determined. However, in order to determine the nature of the invention and the essential elements of the invention, the specification must be construed as a whole. Analysis of a patent is to be determined from the point of view of one skilled in the art, with a mind willing to understand the invention.

Even though claims are construed with reference to the description, reference to the description is only permitted to assist the understanding of terms used within the claims if these terms have a unique meaning. Reference to the description is not permitted for terms that have a plain, common, and unambiguous meaning as these terms would be known to someone of skill within the art, nor is reference to stray phrases within the description considered support for terms within the claims. Furthermore, reference to the description cannot be used to vary the scope of the claims.

The application of these principles can be found in the following: Beecham v Procter Gamble 1982; AT &T v Mitel 1989; Airscal v M&I Heat 1993; Hi-Quail v Rea's Welding 1994; Mobil Oil v Hercules 1994; Cochlear v Cosem; and Almecon v Nutron 1996.

11.03 Clarity March 1998

No speculation should be necessary to determine what is covered by each claim. It must not define some parts of the desired monopoly while only alluding to or vaguely mentioning others. If the invention is difficult to claim, due allowance is given for the limitations of language but involved language should not be used when the invention can be claimed simply. Wording should not be so flexible that several interpretations of it are possible, i.e. the claim should not have more than one meaning or be capable of both broad and narrow interpretations.

11.03.01 Antecedents

When an element is referred to in definite terms without having been introduced previously, the claim is objectionable under section 27(4) of the *Patent Act*. An example of this is, "A device for cracking nuts comprising a cup shaped base and a striker element, said lever tripping the hammer at timed intervals". In this claim there are no proper antecedents for "said lever" and "the hammer".

Implied antecedents may be permitted where the word or phrase, by definition, always contains the missing antecedent. For example, a claim beginning with: "A wheel, the axis being..." or "A compound having the formula I..." are acceptable.

11.03.02 Ambiguity in claims

The claims must be framed in distinct and clear language. They should not include vague or equivocal forms of wording which will create doubt. Examples of unclear language are relative terms or expressions such as "thin", "strong", "a major part", "if desired". If such expressions appear in a claim, they must be further defined in clear and distinct terms or be removed from the claim.

The following are some of the most commonly used imprecise terms that may be encountered in claims:

a) "Such as", "Or the like", "For example".
b) "If desired", "When required".
c) "About", "Approximately", "More or less".
d) "Preferably".

Other terms which in certain circumstances may be indefinite are:

a) "Containing as an active ingredient".
b) "Therapeutically effective amount".
c) "A major part".
d) "Of the character described@, "As herein described".
e) "At least", "At least one of".
f) "And/or", "Either....or".
g) "An effective amount", "A sufficient amount", "A synergistic amount".
h) "Not being...", "Not having...", "Not requiring...".

Whenever any of the above terms is encountered in a claim, a possibility exists that the claim may not satisfy the requirements of the *Patent Act* and Rules. Specifically, subsection 27(4) of the *Patent Act* and Section 84 of the *Patent Rules* should be considered.

Some of these terms have been considered in decisions by the courts or by Commissioner's decisions.

a) "Containing as an active ingredient"
This phrase should, in some circumstances be refused as being ambiguous and indefinite because "an" implies the presence of other unspecified active ingredients in addition to the one specified in the claim.

Note: This phrase would be acceptable in a claim if "an" is changed to "the" and the other ingredients of the composition are specified while the utility for which the composition is intended is either inherent from the wording of the claim or expressly stated therein (Rohm & Haas v. Commissioner of Patents 30 C.P.R. 113, Ex.C.).

(b) "Therapeutically effective amount"

As was stated in Gilbert v. Sandoz 64 C.P.R. 14, Ex.C., this is an ambiguous term in a claim. The claims in suit included this phrase in conjunction with a particular phenothiazine derivative when produced by specified process claims in association with a pharmaceutical carrier. While it is recognized that the essence of a great many inventions based on compounds for medicinal purposes resides more in the discovery of the unexpected medicinal utility of the compound than in its effective dose, nevertheless, when such a functional statement occurs in a claim, the medicinal utility of the composition of matter must be stated or be inherent from the preamble of the claim.

A particular amount of an active ingredient in combination with another compound (X) may have an entirely different therapeutic value than a very different amount of the same active ingredient in combination with compound X. Therefore, this functional phrase should only be permitted in a composition of matter claim when the utility of the composition of matter is indicated in the claim and provided that the actual amount taught and prescribed in the disclosure is not an important aspect of the invention. This amount may vary over a considerable range apparent to one skilled in the art because of similar known ranges for analogous compounds for the same purpose. However, if the disclosed range is an important feature of the invention or if the invention is only operable within a prescribed range so as to produce the promised results, then of course this disclosed range must be included in all of the independent claims.

(c) "A major part"

This is an acceptable phrase in a claim if it is used in relation to one part of a two- part system where it is clear that it means more than 50%. However, when it refers to one part in a system consisting of three or more parts, it is refused as indefinite because it is not clear if it means a greater percentage than any of the other components or more than 50% of the overall total.

11.03.03 Negative limitations

Claims containing negative expressions such as "not being...", "not having...", "not requiring..." may be objectionable under section 27(4) of the *Patent Act* in that claims should generally set forth what the invention is or does, and not what it is not or does not do, unless there is no positive way to describe it. Sometimes a dependent claim (Chapter 11.06) contains provisions which effectively cancel or negate some of the features of a preceding claim, thus making the dependent claim broader than the preceding claim. This is objectionable under section 87 of the *Patent Rules*.

11.04 Completeness of claims March 1998

To define the invention distinctly and in explicit terms, it is required that sufficient elements be recited for operability. The inventive features must appear in each claim . In the case of a composition, a claim must define a minimum of two ingredients, at least broadly. If a claim does not do this, it is objected to as indefinite and contrary to subsection 27(4) of the *Patent Act*.

11.05 Support March 1998

A claim must be fully supported by the description as required by section 84 of the *Patent Rules*. All the characteristics of the embodiment of the invention which are set forth in the claim must be fully set forth in the description (Section 84 of the *Patent Rules*). However, since the claims included in the application at the time of filing are part of the specification (see definition of specification in section 2 of the *Patent Rules*), any matter in the originally filed claims that was not included in the description as filed may be added to the description.

A claim is objected to for lack of support by the description if the terms used in the claim are not used in the description and cannot be clearly inferred from the description. Terms used in the claims and in the description must be used in the same sense.

11.05.01 Claims referring to description or drawings

It is generally not acceptable for a claim to contain reference to the description or drawings (subsection 86(1) of the *Patent Rules*). However, in some instances, if the claim is complete in itself and can be read and understood without the reference, the claim is acceptable. The claims must not, in respect of the technical features of the invention, rely on references to the description or drawings except where absolutely necessary. In particular, they must not rely on references such as: "as described in the description " or "as illustrated in Figure 3". The following are examples of exceptions:

(a) Claims which include reference numerals

Reference numerals used in the drawings are permissible in a claim provided they are in brackets or parenthesis (subsection 86(2) of the *Patent Rules*), and the claim is otherwise explicit and complete. However, if a claim is not complete without referring to the parts of the drawings identified by numerals in brackets, it must be objected to as contravening subsection 27(4) of the *Patent Act*.

(b) Claims which make reference to charts, tables and graphs

Tabulations in the form of charts often appear in the descriptions of applications. Such tabulations may also be included in the drawings as are graphs, phase diagrams, absorption spectrograms and the like. In circumstances where the nature of the invention is very complex and it is practically impossible or extremely cumbersome to define the scientific relationship of the different factors in a precise and distinguishing manner, without making reference to other parts of the application, then reference to charts, graphs or tables may be permitted in the claims. However, if such a chart or table, for example, is brief and concise, i.e. about 5-10 lines, the applicant may be required to enter it into the claims (subsection 86(1) of the *Patent Rules*).

(c) Reference to particular unconventional disclosed tests

If a test can be accurately defined in a few lines, then it must be included in the claim and a mere reference to such a test as described should not be permitted. However, when such a test is complex and lengthy to describe, for example if it requires more than one page of the description to characterize it, then the applicant may make reference to the test as therein defined rather than reproduce the test in the claim.

(d) Reference to Sequence listings and Biological Deposits

Reference may be made, within a claim, to sequence listing identifier numbers and biological deposit catalogue numbers (subsections 86(3) and (4) of the *Patent Rules*). These procedures are specified in detail in chapter 17 (Biotechnology).

11.05.02 Scope in relation to description

A claim may be as narrow as the applicant wishes within the scope of the invention disclosed. It must not, however, be broader than the invention as described or supported by the description. Furthermore, a claim will fail if, in addition to claiming what is new and useful, it also claims something that is old or useless (Mineral Separation v. Noranda Mines 12 C.P.R. 99; 12 C.P.R. 182; 15 C.P.R. 133).

Each claim must be read giving its words the meaning and scope which they normally have in the relevant art, unless in particular cases the description gives the words a special meaning by explicit definition. If a claim covers subject matter outside the scope of the described invention, it should be objected to for failing to satisfy the provisions of section 84 of the *Patent Rules*.

11.05.03 Ranges not specifically described

When an application includes claims containing a specific limitation with respect to operating conditions, which limitation falls within a broader range described, no objection is made to the narrow claim solely on the grounds that it is not specifically shown in the description or that the description does not indicate the significance of the described range. For example, an application may describe a process carried out within certain temperature limits, e.g. between 500°C and 800°C. No objection is made if some claims are directed to the process carried out between 500°C and 800°C and others to the process carried out at a temperature falling within a smaller range within the described range, e.g. between 650°C and 700°C. However, should the broad claim fall in view of prior art, the narrower claim would also fall unless it can be shown that by restricting the process to the narrower range, a new and unobvious result is obtained.

11.06 Dependent claims March 1998

Section 87 of the *Patent Rules* permits a claim to refer to one or more other claims, in order to define an invention more narrowly by adding further characteristics to those already present in the claims to which reference is made. Such a claim is designated as a dependent claim.

Claims are also permitted to refer to other claims or parts of claims of the same or of another category, in order to avoid repeating lengthy definitions already given and to simplify claiming, provided they do not become ambiguous as a result of such dependency, thereby contravening section 27(4) of the *Patent Act*. Such claims however are not dependent claims and section 87 of the *Patent Rules* does not apply. The patentability of the claim referred to does not necessarily imply the patentability of the dependent claim containing the reference. The following example indicates the form of claiming that is acceptable.

Claim 1: A product comprising composition A.

Claim 2: A process for the production of the composition defined in claim 1 comprising reacting B with C.

An objection is made whenever there is uncertainty as to which part of a preceding claim reference is made or whenever a dependent claim of one category, such as a process, contains by reference so many limitations of another category, such as a product, that it becomes difficult to determine which category the claim covers.

A dependent claim usually refers to other claims in its preamble. In view of subsection 87(1) of the *Patent Rules*, a dependent claim must state the additional features claimed. According to subsection 87(3) of the *Patent Rules*, a dependent claim is understood as including all the limitations inherent in the particular claim or claims in relation to which it is considered. When a claim refers to other claims it must only refer to preceding claims and it must do so to by number.

Examples:

Claim 1: The process of reacting A with B in the presence of a catalyst. (acceptable)

Claim 2: The process of reacting A with B in the presence of a metal containing catalyst. (acceptable)

Claim 3: The process of claim 2 in which the catalyst contains iron. (acceptable)

Claim 4: The process of claim 3 in which the catalyst also contains copper. (acceptable)

Claim 5: The process of claim 1, 2, 3, or 4 in which the catalyst also contains zinc. (acceptable)

Claim 6: The process of any one of claims 1 to 5 in which the catalyst also contains cobalt. (acceptable)

Claim 7: The process of any of the above claims in which the catalyst is supported on an inert carrier. (not acceptable)

Claim 8: The process of claim 5 in which the catalyst is supported on an inert carrier. (acceptable)

Claim 9: The process of claim 6 in which the catalyst is supported on an inert carrier. (acceptable)

Claim 10: The process of claim 8 or 9 in which the inert carrier is a silica. (acceptable)

Claim 11: The process of claims 3 and 4 in which the catalyst also contains manganese. (acceptable)

In the examples given above, no objection would be taken to claims 1-6 and 8-10 in view of the provisions of section 87 of the *Patent Rules*. In contrast, claim 7 which does not refer to the preceding claims by number, would, consequently, violate subsection 87(1) of the *Patent Rules* and would therefore be objected to.

The form of dependent claims accepted under section 87 of the *Patent Rules* will be considered acceptable in all applications presently pending in the Patent Office.

11.07 Combinations March 1998

A combination is a union of elements or process steps co-operating to produce a unitary and practical result that is not the sum of the known characteristics of the elements or steps.

A patentable combination is one in which the elements or steps cooperate in an unexpected manner or cooperate in a known way to give an unobvious result or effect. If all the requirements of the *Patent Act* and Rules are met, a claim to such a combination can be allowed.

A subcombination is part of a combination. It may be a single element or step of the combination or may, itself, be a combination.

11.07.01 Exhaustive combinations

Claims must not exceed the scope of the invention by going further than the protection to which the inventor is entitled. Generally, an inventor is entitled to claim the invention, be it apparatus, product or method and its immediate and cooperating environment. For example, claims to a new accelerator pump and the carburetor containing it are permitted. Also, claims to a new type of radio tube grid may be permitted with claims to the tube containing the grid. But claims to a new pump in a carburetor which is attached to an engine or claims to a radio receiver accommodating a tube having a new grid would be objected to unless the overall combination produced new and unexpected results, amounting to further invention, that may require restriction under section 36 of the *Patent Act*.

11.07.02 Aggregation

The information in this subsection has been moved to subsection 15.02.04 of this manual.

11.08 Product claims March 1998

In product claims, the product may be defined in three ways:

(i) By structure. In the chemical field this includes empirical formulae, structural formulae, and chemically acceptable names.
(ii) In terms of the process by which it is made. These are known as product-by-process claims.

(iii) In terms of physical or chemical properties.

A claim that defines a product by a mixture of two or three of these forms is also possible.

The most explicit and definite form of claims for a product defines the product by structure. Since, under subsection 27(4) of the *Patent Act*, the applicant is required to distinguish any new product from all other products by claiming it distinctly and explicitly, the structure, if known, should be given in the claim.

11.08.01 Product-by-process claims

A product-by-process claim defines the claimed product wholly or partly in terms of the process used to produce the product. The process limitations may be included within the product claim itself or the whole claim may be made dependent upon another claim directed to the process. The following examples show the two possible forms:

(i) The product made by heating A with B.

(ii) The product when made by the process of claim 1.

The use of past participle adjectives, such as welded, bent, molded or coated, is not construed as changing a product claim into a product-by-process claim.

A product-by-process claim, where permitted, must define the product explicitly and distinguish it from all other products. Hence, products that are already known may not be claimed by making them dependent on a new process (Hoffman-La Roche v. Commissioner of Patents 23 C.P.R. 1).

A product-by-process claim must be directed to the final product of the process claim upon which the product claim is made dependent.

11.09 Means claims March 1998

A "means" claim is one in which at least part of an invention is defined as a means or mechanism for performing an act, instead of reciting the element that performs the action.

Invention may exist in a new combination of old means (Lightning Fastener v. Colonial Fastener 51 RPC 349; Martin and Biro Swan v. H. Millwood 1956 RPC 125). Claims composed of more than one statement of old means are allowable, without defining structure, if there is invention in the new combination.

If a claim is composed of a single statement of means, it is objected to for being indefinite and contrary to subsection 27(4) of the *Patent Act*. The report of the examiner should indicate in detail why the claim contravenes subsection 27(4) of the *Patent Act*. It may, for example, be directed to the result desired rather than to the combination developed and illustrated to achieve that result.

A claim is also objected to if it contains a broad means statement at the point of invention, i.e., a statement that distinguishes the claim from the prior art, but which is so broad that it embraces all possible means without qualification for solving the problem facing the inventor and is in effect no more than a restatement of the problem or desired result.

Examples:

An application describes a sanding device that may be used in a direct-drive mode for removing stock from a work piece at a rapid rate or in an orbital mode for removing stock at a much slower rate to provide a smooth finish. The invention lies in the combined use of a known one-way clutch and a known reversible motor in an otherwise conventional rotary sander. Under prior art conditions, either two sanders were used or an attachment was employed to convert a device from a direct-drive sander to an orbital sander.

Claim (i) Means for operating a sanding device in either a direct-drive mode or an orbital mode.

This claim would be objected to under section 27 of the *Patent Act*. The applicant should claim a sander having the combination of a one-way clutch with a reversible motor.

Claim (ii) A surface-finishing device comprising a drive shaft, a driven element connected to receive drive from the drive shaft, a driven shaft mounted for rotation in said driven element about an axis eccentric to the axis of the drive shaft, means connecting the driven shaft to the driven element, a surface-finishing tool connected to be driven by the driven shaft, and automatic means for selectively connecting the surface-finishing tool directly to the drive shaft, or allowing said tool to rotate freely in an orbital path about the drive shaft axis.

This claim would be objected to for merely restating the desired result.

Claim (iii) A surface-finishing device comprising a drive shaft, a driven element connected to receive drive from the drive shaft, a driven shaft mounted for rotation in said driven element about an axis eccentric to the axis of the drive shaft, one-way clutch means connecting the driven shaft to the driven element, a surface-finishing tool connected to be driven by the driven shaft, and means for selectively driving the drive shaft in one direction or in an opposite direction.

This claim would be accepted as a novel combination of known means giving a new and unexpected result.

11.10 Process, method, method of use and use claims March 1998

The Patent Office accepts process, method, method of use and use claims as explained under the following subheadings.

11.10.01 Process and method claims

A method is the series of steps to be followed either alone or in conjunction within a process in order to achieve a desired result. A method should be distinguished from a process, which includes the method and the substances to which it is applied. The overall process may be new even though the method is old.

A claim to a process which consists of applying a known method to chemically react known substances is patentable, providing the method has never before been applied to these substances and results in new, useful and unobvious products. (Ciba Ltd. v. Commissioner of Patents 27 C.P.R. 82; 30 C.P.R. 135).

11.10.02 Method of use and use claims

When a claim to a compound has been found allowable in an application, then a claim to a method of use of that compound or a claim to the use of that compound is also allowable in the same application. When a claim to a compound has been found allowable to the inventor in one application, then claims in a different application of the same inventor to a use of that compound or methods of using that compound which are obvious from the utility disclosed for the compound, and upon which utility the patentability of the compound was predicated, are not allowed.

When a compound has been patented previously or is in the public domain, claims directed to the obvious use of this compound should be objected to for lacking patentable subject matter. Claims directed to a new and unobvious use of the same compound are allowable. Likewise, claims directed to a method of using the compound for a new unobvious purpose are allowable. Furthermore, when an invention is directed to a novel and unobvious use of a known compound, claims to this known compound with the further recitation of a novel use are allowable (re application for patent of Wayne State University 22 C.P.R. (3d) 407).

When a device or machine is only a new instrument for carrying out an old method, only the device or machine can be patented. Since the utility of a device or machine is obvious from the description of the device or machine, the patentability of a method using such device or machine is determined by the state or the art.

Guidelines for method of use claims

(i) Method of use claims directed to medicinal use are rejected under Section 2 of the *Patent Act* in view of Tennessee Eastman v. Commissioner of Patents (1970) 62 C.P.R. 117; (1974) S.C.R. 111.

Example: Method of treating the symptoms of cognitive decline in a patient comprising administering to a patient an effective amount of compound X wherein said compound is used as a cholinergetic agent. (rejected)

(ii) Method of use claims directed to a medicinal treatment should be interpreted to include only those methods directed to curing or preventing diseases in humans or animals. Method claims directed to an industrial use should not be rejected.

Example: Method for enhancing the dressed carcass weight of meat-producing animals by increasing lean meat deposition and improving the lean meat to fat ratio comprising administering to said animals, before slaughter, either orally or parenterally, an effective amount of a compound X. (accepted)

(iii) Other types of method of use claims directed to an industrial use are allowable but must include manipulative steps. (The reasoning for the requirement of the presence of manipulative steps is to distinguish method of use claims from use claims.)

Example: Method of using compound X as an intermediate to prepare compound Y wherein compound X is reduced by hydroboration or catalytic hydrogenation. (accepted)

(iv) Method of use claims incorporating a use are also acceptable as long as they meet the requirement of a proper method claim (i.e., include a manipulative step). (accepted)

Example: Method of controlling agricultural bacteria which comprises incorporating into the locus to be treated an effective amount of compound X wherein said compound is used as a bacterial agent. (accepted)

(v) Similarly, product claims containing either a use or method definition are acceptable, provided that the method is not a method of medical treatment).

Example: Compound X for the use as an insecticide wherein said compound is applied to the locus of a tree trunk, (accepted).

Example: Compound Y for the treatment of viruses wherein said compound is administered to a patient intravenously, (not accepted because it contains a method of medical treatment).

Guidelines for use claims

(i) Use claims are permitted. Moreover, use claims incorporating method steps are acceptable as long as the use has been clearly identified and it is not a method of medical treatment. If the claim is complete and understandable without the method steps, then the claim as a whole is acceptable. The method steps merely provide a restriction to the previously recited use.

Example: Use of compound X as a herbicide. (accepted)

Use of compound X as a herbicide wherein an effective amount of the compound X is incorporated into the locus to be treated. (accepted)

Use of compound Y as an antiarrhythmic agent. (accepted)

Use of compound Y as an antiarrhythmic agent wherein an effective amount of the compound Y is administered to a patient. (not accepted). The addition of the "wherein" clause makes the use a method of medical treatment.

Use of machine Z for cutting. (accepted)
Use of machine Z for cutting wherein ... (accepted)

11.11 Markush claims March 1998

In chemical cases, a claim directed to a genus expressed as a group consisting of certain specified materials is allowable (Ex parte Markush 1925, 340 U.S.O.G. 839) provided it is clear from the known nature of the alternative materials or from the prior art that the materials in the group possess at least one property in common which is mainly responsible for their function in the claimed relationship. Therefore, a Markush claim will generally be construed with a generic expression covering a group of two or more different materials (elements, radicals, compounds) as illustrated in the following examples:

> A solvent selected from the group consisting of alcohol, ether and acetone...
>
> A strip of a conductive metal selected from the group consisting of copper, silver and aluminium...

Occasionally, the Markush format may be used in claims directed to subject matter in the mechanical or electrical fields in a manner such as that illustrated in the example below:

> A means for attaching a wall panel to a framework wherein the attaching means is **selected from group consisting of** nails, rivets **and** screws...

11.12 Selection patents March 1998

The information in this subsection has been moved to section 15.07 of this manual.

11.13 Jurisprudence March 1998

The following decisions of the courts are of importance in considering the subject matter of this chapter:

claims construction

Mineral Separation v Noranda	12 CPR	99	1950
	69 RPC	81	1952
O'Cedar v Mallory Hardware	ExCR	299	1956
McPhar v Sharpe	35 CPR	105	1960
Metalliflex v Wienenberger	35 CPR	49	1961
	SCR	117	1961
Lovell v Beatty	41 CPR	18	1962
Burton Parsons v Hewlet	1 SCR	555	1976
Xerox v IBM	33 CPR (2d)	24	1977
Cutter v Baxter Travenol	68 CPR (3d)	179	1983
Johnston Controls v Varta	80 CPR (2d)	1	1984
Reading & Bates v Baker	18 CPR (3d)	181	1987
AT&T Tech v Mitel	26 CPR (3d)	238	1989
Energy v Boissonneault	30 CPR (3d)	420	1990
Lubrizol v Imperial Oil	33 CPR (3d)	11	1990
	45 CPR (3d)	449	1992
Computalog v Comtech	32 CPR (3d)	289	1990
	44 CPR (3d)	77	1992
Procter & Gamble v Kimberly	40 CPR (3d)	1	1991
Welcome v Apotex	39 CPR (3d)	289	1991
TRW Inc v Walbar	39 CPR (3d)	176	1991
Martinray v Fabricants	14 CPR (3d)	1	1991
Reliance v Northern Tel	47 CPR (3d)	55	1993
Airseal v M&I Heat	53 CPR (3d)	259	1993
Dableh v Ont Hydro	50 CPR (3d)	290	1993

Unilever v Procter & Gamble	47 CPR (3d)	479	1993
	61 CPR (3d)	499	1995
Nekoosa v AMCA Int	56 CPR (3d)	470	1994
Anderson v Machineries	58 CPR (3d)	449	1994
Pallmann v CAE	62 CPR (3d)	26	1995
Hi-Quail v Rea's Welding	55 CPR (3d)224		1994
Feherguard v Rocky's	53 CPR (3d)	417	1994
	60 CPR (3d)	512	1995
Cochlear v Coseum	64 CPR (3d)	10	1995
Pallmann v CAE	62 CPR (3d)	26	1995
Almecon v Nutron	65 CPR (3d)	417	1996

positive recitation

Mineral Separation v Noranda	12 CPR	99	1950
	69 RPC	81	1952
Burton Parsons v Hewlet	1 SCR	555	1976
Eli Lilly v O'Hara	20 CPR (3d)	342	1988
	26 CPR (3d)	1	1989
Hi-Quail v Rea's Welding	55 CPR (3d)224		1994
Pallmann v CAE	62 CPR (3d)	26	1995

antecedents

Mobil Oil v Hercules	57 CPR (3d)	488	1994
	63 CPR (3d)	473	1995

preamble

Re: Lelke	72 CPR (2d)	139	1981
Shell Oil v Comm of Pat	2 SCR	536	1982
Rucker V Gavels Vulcanizing	7 CPR (3d)	294	1985
Permacon v Enterprises	19 CPR (3d)	378	1987
Re: Neuro Med Inc	28 CPR (3d)	281	1988
Computalog v Comtech	44 CPR (3d)	77	1992

explicit, distinct v ambiguous/several interpretations

Rohm & Haas v Comm of Patents	30 CPR	113	1959
Xerox v IBM	33 CPR (2d)	24	1977
Monsanto v Comm of Pat	42 CPR (2d)161		1979
	2 SCR	1108	1979
Ciba Geigy v Comm of Pat	65 CPR (3d)	73	1982
Pioneer Hi-Bred v Com of Pat	14 CPR (3d)	491	1987
	25 CPR (3d)	257	1987
Reliance v Northern Tel	28 CPR (3d)	397	1989
	44 CPR (3d)	161	1992
	47 CPR (3d)	55	1993
Risi Stone v Groupe Peracon	29 CPR (3d)	243	1990
	65 CPR (3d)	2	1995
Allied v Du Pont	52 CPR (3d)351		1993
	50 CPR (3d)	1	1993
Mobil Oil v Hercules	57 CPR (3d)	488	1994
	63 CPR (3d)	473	1995

insufficient/sufficient/essential elements

BVD Co V Canadian Celanese	ExCR	139	1936
	SCR	221	1937
Mineral Separation v Noranda	12 CPR	99	1947
	15 CPR	133	1952
Curl Master v Atlas Brush	SCR	514	1967
Burton Parsons v Hewlet	1 SCR	555	1976
Re: Farbwerke Hoechst	13 CPR (3d)	212	1980
Ciba Geigy v Comm of Pat	65 CPR (3d)	73	1982
Consolboard v MacMillan	56 CPR (2d)145		1981
	1 SCR	504	1981
Ductmate v Exanno	2 CPR (3d)	289	1984
Amfac Foods v Irving Pulp	12 CPR (3d)	193	1986
Crila Plastics v Ninety Eight	10 CPR (3d)	226	1986
	18 CPR (3d)	1	1987
Reliance v Northern Tel	28 CPR (3d)	397	1989

	44 CPR (3d)	161	1992
	47 CPR (3d)	55	1993
TRW Inc v Walbar	39 CPR (3d)	176	1991
Atlas v CIL	41 CPR (3d)	348	1992
Airseal v M&I Heat	53 CPR (3d)	259	1993
Mobil Oil v Hercules	57 CPR (3d)	488	1994
	63 CPR (3d)	473	1995
Feherguard v Rocky's	53 CPR (3d)	417	1994
	60 CPR (3d)	512	1995

operability

Union Carbide v Trans Canadian	ExCR	884	1965
Mineral Separation v Noranda	12 CPR	99	1950
	69 RPC	81	1952
Gilbert (Gillcross) v Sandoz	64 CPR	14	1970
	SCR	1336	1974
Burton Parsons v Hewlet	1 SCR	555	1976
Sandvick v Windsor	8 CPR (3d)	433	1986
Mahurkar v Vas-Cath	18 CPR (3d)417		1988
Welcome v Apotex	39 CPR (3d)	289	1991
TRW Inc v Walbar	39 CPR (3d)	176	1991
Feherguard v Rocky's	53 CPR (3d)	417	1994
	60 CPR (3d)	512	1995
Mobil Oil v Hercules	57 CPR (3d)	488	1994
	63 CPR (3d)	473	1995

broad

BVD Co V Canadian Celanese	ExCR	139	1936
	SCR	221	1937
Trubenizing v John Forsyth	2 CPR	1	1943
O'Cedar v Mallory Hardware	ExCR	299	1956
Lovell v Beatty	41 CPR	18	1962
Boehringer v Bell-Craig	39 CPR	201	1962
Union Carbide v Trans Canadian	ExCR	884	1965

Hoechst v Gilbert		SCR	189	1966
Gilbert v Sandoz		64 CPR	14	1970
Burton Parsons v Hewlet		1 SCR	555	1976
Monsanto v Comm of Pat		42 CPR (2d)161		1979
		2 SCR	1108	1979
Re: American Home Products		55 CPR (2d)	238	1980
Re: Farbwerke Hoechst		13 CPR (3d)	212	1980
Cutter v Baxter Travenol		50 CPR (2d)	163	1980
		68 CPR (3d)	179	1983
Johnston Controls v Varta		80 CPR (2d)	1	1984
Sandvick v Windsor		8 CPR (3d)	433	1986
Amfac Foods v Irving Pulp		12 CPR (3d)	193	1986
Cabot Corp v 318602 Ont		20 CPR (3d)	132	1988
Mahurkar v Vas-Cath		18 CPR (3d)417		1988
Reliance v Northern Tel		28 CPR (3d)	397	1989
		44 CPR (3d)	161	1992
		47 CPR (3d)	55	1993
		55 CPR (3d)	299	1994
Risi Stone v Groupe Peracon		29 CPR (3d)	243	1990
Lubrizol v Imperial Oil		33 CPR (3d)	1	1990
		45 CPR (3d)	449	1992
Welcome v Apotex		39 CPR (3d)	289	1991
Dableh v Ont Hydro		50 CPR (3d)	290	1993
Unilever v Procter & Gamble		47 CPR (3d)	479	1993
		61 CPR (3d)	499	1995
Mobil Oil v Hercules		57 CPR (3d)	488	1994
		63 CPR (3d)	473	1995
Nekoosa v AMCA	Int	56 CPR (3d)	470	1994
Pallmann v CAE		62 CPR (3d)	26	1995
Almecon v Nutron		65 CPR (3d)	417	1996

selection/improvement

Sherbrooke v Hydrolic	Ex CR	114	1927
Bergeon v De Kermor	Ex CR	181	1927
Western Electric v Bell	Ex CR	213	1929

Wandscheer v Sicard	SCR	1	1948
K v Uhleman Optical	Ex CR	142	1950
	1 SCR	143	1952
O'Cedar v Mallory Hardware	Ex CR	299	1956
Ciba Geigy v Comm of Pat	27 CPR	82	1957
	30 CPR	135	1959

aggregation/combination

Lightning Fastener v Colonial	Ex CR	89	1932
	SCR	63	1933
	51 RPC	349	1934
Crosley Radio v CGE	SCR	551	1936
Lanlois v Roy	Ex CR	197	1941
Lester v Comm of Pat	Ex CR	603	1946
Wandscheer v Sicard	Ex CR	112	1946
	SCR	1	1948
R v Uhleman Optical	Ex CR	142	1950
	1 SCR	143	1952
Defrees v Dominion Auto	Ex CR	331	1963
Barton v Radiator Specialty	44 CPR	1	1965
Gibney v Ford	2 Ex CR	279	1972
Rubbermaid v Tucker Plastics	8 CPR (2d)	6	1972
Agripat v Comm of Patents	52 CPR (2d)	229	1977
Domtar v MacMillan	33 CPR (2d)	182	1977
Xerox v IBM	33 CPR (2d)	24	1977
Ductmate v Exanno	2 CPR (3d)	289	1984
Windsurfing v Triatlantic	3 CPR (3d)	95	1984
Hy Kramer v Lindsay	9 CPR (3d)	297	1986
Crila Plastics v Ninety Eight	10 CPR (3d)	226	1986
	18 CPR (3d)	1	1987
Hoffman-La Roch v Apotex	15 CPR (3d)	217	1987
	24 CPR (3d)	289	1989
Standal v Swecan	28 CPR (3d)	261	1989
Imperial Tobacco v Rothmans	47 CPR (3d)	188	1993

Chapter 12
Subject-Matter and Utility

12.01 Statutory subject-matter November 2017

The protection offered by the *Patent Act* extends to many but not all types of human endeavour; those types to which it applies are called “statutory”. Section 2 of the *Patent Act* defines an invention as:

> *any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.*

In order to be considered statutory, the subject-matter for which protection is sought must fall within one of these categories of subject-matter defined in section 2 of the *Patent Act*. The requirement that an invention be statutory can be framed in terms of asking whether or not the invention is proper “subject-matter” for a patent.

12.01.01 Art

The term “art”, for the purposes of the *Patent Act*, pertains to the application of knowledge to effect a desired result.[1] To be statutory, an “art” must be what the courts have termed a “useful art”[2] and a “manual or productive art.”[3] An art must be the practical application of knowledge,[4] and must therefore be defined in a manner that gives practical effect to the knowledge. An art, therefore, is typically claimed as either a use or a method.

A use claim typically sets out a manner or mode of employing something in order to accomplish a particular result without prescribing in detail how the result is to be achieved. For example, a use claim might take the form “Use of a heat source to boil water.” [See Chapter 11 for further guidance on use claims.]

A "method" claim also sets out a mode or manner of accomplishing a certain result but includes one or more particular steps required to achieve the result. For example, a method claim might take the form of "A method of heating water comprising the steps of pouring two cups of water into a stainless steel container, placing the container on a heat source, and heating the water until the water temperature reaches 100 degrees Celsius."

Whether or not a method is statutory is not determined by whether or not it produces a statutory product.

12.01.02 Process

A "process" implies the application of a method to a material or materials.[5] A process can be considered to be a mode or method of operation by which a result or effect is produced by physical or chemical action, by the operation or application of some element or power of nature; or of the application of one substance to another. As with methods, whether or not a process is statutory is not determined by whether or not it produces a statutory product.

12.01.03 Machine

A "machine" is the mechanical and/or physical embodiment of any function or mode of operation designed to accomplish a particular effect, wherein the parts of the machine cooperate to accomplish the effect. A machine can be considered to be "any device that transmits a force or directs its application", or "a device that enables energy from one source to be modified and transmitted as energy in a different form or for a different purpose".[6] A machine may be claimed as a device, as an apparatus, or a system, for example.

12.01.04 Manufacture

A “manufacture” has been broadly defined as “a non-living mechanistic product or process” and as being the process of making (by hand, by machine, industrially, by mass production …) technical articles or material (in modern use on a large scale) by the application of physical labour or mechanical power; or the article or material made by such a process.[7]

12.01.05 Composition of matter

A “composition of matter” refers to physical and/or chemical substances, compounds and compositions, and includes combinations of ingredients, whether combined as a chemical union or physical mixture. The term “matter” implies that the ingredients must be perceptible in space and have mechanical mass. In *Harvard College v. Canada (Commissioner of Patents)*, the Supreme Court noted that the scope of this category must be limited in some way, else the categories of "machine" and "manufacture" would be made redundant.[8]

12.02 Inventions must not be disembodied November 2017

An invention is a solution to a practical problem. In order to solve a practical problem, the solution must be something with physical existence, or something that manifests a discernible effect or change[9] and, hence, that will itself enable a person skilled in the art to obtain the intended result or benefit. Such a form is referred to herein as a "practical form" or a "practicable form".

A disembodied idea, concept or discovery that underlies or leads to an invention is not itself patentable; in order to be patentable it must be incorporated in a practical form. A mere idea or intellectual concept, no matter how well it may have been worked out and structured in the mind, is disembodied and is notsomething with physical existence, or something that manifests a discernible effect or change.. In *Shell Oil Co. v. Commissioner of Patents* the Supreme Court noted that "a disembodied idea is not per se patentable. But it will be patentable if it has a method of practical application."[10] In *Riello Canada Inc. v. Lambert*, the court cited with approval comments from *Reynolds v. Herbert Smith & Co., Ltd.*, which noted that "the idea that leads to an invention is [...] no part of the invention. The idea, or the recognition of the want, stimulates the inventor to do something else. It is the something further which he does which is the invention" and similarly that "discovery adds to the amount of human knowledge, but it does so only by lifting the veil and disclosing something which before had been unseen or dimly seen. Invention also adds to human knowledge, but not merely by disclosing something. Invention necessarily involves also the suggestion of an act to be done, and it must be an act which results in a new product, or a new result, or a new process, or a new combination for producing an old product or an old result".[11]

12.03 Excluded subject-matter November 2017

It is apparent from the definition of invention in section 2 of the *Patent Act* that not everything can be patented. With respect to section 2, the Supreme Court noted in *Harvard College v. Canada* that "[b]y choosing to define invention in this way, Parliament signaled a clear intention to include certain subject-matter as patentable and to exclude other subject-matter as being outside the confines of the Act."[12]

The following sections set out various statutory and jurisprudential proscriptions to the scope of patentable subject-matter under section 2 of the *Patent Act*.

12.03.01 Scientific principles and abstract theorems

Subsection 27(8) of the *Patent Act* states:

> *No patent shall be granted for any mere scientific principle or abstract theorem.*

This subsection has been interpreted by the courts as excluding from patentability (*inter alia*) mathematical formulae[13], natural phenomena and laws of nature.

The exclusions of this subsection apply when an attempt is made to claim the excluded subject-matter in a general sense, but not when a scientific principle, law of nature or mathematical formula is relied upon in operating a practical form of an invention.

The Patent Office considers that mere scientific principles and abstract theorems do not constitute an invention within the meaning of section 2 of the *Patent Act*. Accordingly, claims that are found to be directed to scientific principles or abstract theorems will be identified as defective under both subsection 27(8) and section 2 of the *Patent Act*.

12.03.02 Methods of medical treatment or surgery

A method or process of surgery or therapy on living humans or animals is not considered to be within the scope of the meaning of invention as set out in section 2 of the *Patent Act*.

A detailed consideration of medical and surgical methods can be found in chapter 17.

12.03.03 Higher life forms

The Supreme Court of Canada has determined that higher life forms are excluded from patentability by virtue of their not being either manufactures or compositions of matter within the definition of invention as set out in section 2 of the *Patent Act*.[14]

A detailed consideration of higher life forms can be found in chapter 17.

12.03.04 Forms of energy

Forms of energy such as regions of the electromagnetic spectrum, electric currents and explosions are not considered to be subject-matter within the scope of the meaning of invention as set out in section 2 of the *Patent Act*.

Forms of energy are not considered to be manufactures or compositions of matter in the sense intended by the *Patent Act*. Electromagnetic and acoustic signals are also considered to be forms of energy and do not contain matter even though the signal may be transmitted through a physical medium. Thus, claims to electromagnetic and acoustic signals do not constitute statutory subject-matter within the meaning of section 2 of the *Patent Act*.

More particularly, an electromagnetic or acoustic signal is not considered to be an art (i.e. not a method or a use *per se*) nor a process (i.e. not a mode or method of operation by which a result or effect is produced by physical or chemical action; by the operation of application of some element of power of nature; or by the application of one substance to another). Neither is an electromagnetic or acoustic signal a machine, as it is not the mechanical embodiment of any function or mode of operation designed to accomplish a particular effect, nor is it a composition of matter, as it is not a chemical compound, composition or substance. An electromagnetic or acoustic signal is taken not to be itself a material product and is therefore, also not a manufacture.

12.03.05 Features of solely intellectual or aesthetic significance

Features of an invention that have a purely intellectual or aesthetic significance are considered, in a practical sense, not to affect the functioning of the invention. Such features cannot change the manner in which the practical form of an invention operates to solve the problem for which it is the solution.

Where a claim appears to be directed to subject-matter having solely intellectual or aesthetic significance, the claim is defective under section 2 of the *Patent Act*.[15]

Where an invention requires a practical problem to be solved in order to enable a result or effect having solely intellectual or aesthetic significance, the patentability of the invention is not impacted by the fact its purpose is to produce a non-statutory result or effect.[16] In such cases, the practical form of the invention does not lie solely in its intellectual or aesthetic significance as the solution to the practical problem gives rise to a new functionality.

12.03.06 Printed matter

Printed matter that has purely intellectual or aesthetic significance, such as a literary work, is excluded from patentability for the reasons outlined in 12.03.05. However, where printed matter provides a new functionality to the substrate on which it is printed, a claim to this subject-matter may be considered statutory. For the printed matter and the substrate to be considered to be a practical form of an invention, they must solve a practical problem related to the use of the printed matter in general, and not be based solely on the intellectual or aesthetic content of the printed matter itself.

By way of example, each of the following has been found by the Commissioner of Patents as being patentable: a textile material bearing markings to enable greater precision during a manufacturing procedure,[17] a newspaper layout in which white space is left to facilitate reading when the paper is folded, a layout of text on a series of pages to facilitate a bookbinding process, and a layout of text on a ticket which permits the ticket to be divided either horizontally or vertically while ensuring all information will appear on both halves.[18]

In each of the foregoing the printed matter provided a new mechanical functionality to the combination; the actual content of the printed matter was not the basis of the invention. Where printed matter has only intellectual or aesthetic significance, it may conveniently be referred to as "non-functional descriptive matter".

The term "printed matter" should not be restricted to traditional ink-on-paper printing but may include any means of displaying information.

Example:

An application describes a new scratch-off lottery ticket wherein the scratchable areas are arranged in a maze-pattern, wherein the user must scratch one cell at a time to determine if they can move their way to the end of the maze.

Claim:

1. A scratch-off lottery ticket comprising a pattern or a plurality of intersecting pathways that define a maze, said pathways divided into individual cells, each cell including an indicator of direction and each cell being covered by an opaque scratchable material, wherein if the indicators of direction define a path from a first cell of the maze to a final cell of the maze, the lottery ticket is a "winning ticket."

Analysis:

Person of ordinary skill in the art (POSITA)

The POSITA is considered to be a person who is skilled in the design of scratch-off lottery tickets; the POSITA is also knowledgeable in the field of marketing.

Common General Knowledge (CGK) of the POSITA

The POSITA would consider that substrates on which information is concealed under opaque scratchable material are CGK. The use of such substrates in the art of scratch-off lottery tickets having various game scenarios would also be considered to be CGK.

The Problem

The POSITA, having read the specification and in light of their CGK, would consider that the problem addressed by the claimed invention was to provide a variation on scratchable lottery tickets.

The Solution

The solution to the problem is the provision of the pattern or the plurality of intersecting pathways that define a maze.

What are the essential elements?

The essential element (i.e. the element that provides the solution to the problem) is the pattern or the plurality of intersecting pathways that define a maze.

Is the claim statutory?

This essential element provides no new functionality to the substrate on which it is printed; it is merely printed matter that has solely intellectual or aesthetic significance. The claim is directed to non-statutory subject-matter and is therefore non-compliant with section 2 of the *Patent Act*.

12.03.07 Fine arts

A fine art has been described as "that having intellectual meaning or aesthetic appeal alone".[19] Fine arts are therefore not patentable subject-matter.[20] The term is understood to include activities such as exercising, dancing, acting, writing, teaching, hair dressing, cosmetology, flower arranging, painting pictures and playing musical instruments. Generally, any product derived from a fine art will also be non-statutory.

Fine arts and the products thereof are not a practical form of an invention since they do not solve any practical problem. Typically, the features that distinguish a product produced by a fine art will have purely intellectual or aesthetic significance.

The exclusion from patentability of fine arts does not extend to inventive materials and instruments used in practising a fine art. For example, while an artistic method of painting a picture and the resultant picture are non-statutory, an inventive easel for holding a canvas would be patentable. Similarly, the paints, paint-brushes etc., used in conjunction with the fine art - but not derived from the fine art as the picture is - may be considered to be statutory subject-matter.

12.03.08 Schemes, plans, rules, and mental processes

A scheme, plan, or rule for performing an operation, achieving a result or controlling a method,[21] and a process that is exclusively a series of mental steps[22] (*e.g.*, performing calculations; manipulating data or information to produce data or information having a different purely intellectual meaning or aesthetic significance) are disembodied (abstract) and are not a practical form of an invention regardless of reproducibility.

12.03.09 Games

A manner of playing a game or sport does not solve a practical problem, and a method for playing a game is therefore non-statutory. This is so whether the claimed method is distinguished on the basis of specific rules governing play[23] or in terms of actions to be taken to achieve specific game-related results.

Tools made use of in the playing of a game may themselves be patentable (*e.g.*, a specifically designed table or playing piece or a game board with a particular mechanical function, or combination of such that is patentable on its own merits).

12.04 Utility November 2017

Section 2 of the *Patent Act* requires that an invention be useful. In *AstraZeneca Canada Inc. v Apotex Inc.*, the Supreme Court noted that "[t]he application of the utility requirement in s. 2… is to be interpreted in line with its purpose — to prevent the patenting of fanciful, speculative or inoperable inventions." [24] "For the subject-matter to function as an inventive solution to a practical problem, the invention must be capable of an actual relevant use and not be devoid of utility."[25] "…[A]n invention must 'be useful, in the sense that it carries out some useful known objective' and is not merely a 'laboratory curiosity whose only possible claim to utility is as a starting material for further research'".[26]

In order to determine whether a patent discloses an invention with sufficient utility under s. 2, the Supreme Court rejected the application of the promise doctrine and set out the analysis that should be undertaken by the courts to correctly approach utility: First, identify the subject-matter of the invention as claimed in the patent. Second, ask whether that subject-matter is useful – is it capable of a practical purpose (i.e. an actual result)?[27]

Utility will differ based on the subject-matter of the invention as identified by claims construction. The scope of potentially acceptable uses to meet the s. 2 requirement is limited – not any use will do. The usefulness of a proposed invention must be related to the nature of the subject-matter and cannot be saved by an entirely unrelated use.[28]

The *Patent Act* does not prescribe the degree or quantum of usefulness required, or that every potential use be realized. A single use related to the nature of the subject-matter is sufficient and the threshold that must be met to establish utility is quite low; "a scintilla of utility will do". [29]

Except where utility is the essence of the invention (e.g. new uses for old compounds), an applicant need not expressly set out the utility of the invention in the application;[30] however if an invention's utility is questioned, utility must be shown to have been demonstrated or soundly predicted (see 12.04.03) as of the application's filing date. This ensures that patents are not granted where the use of the invention is speculative.[31]

To be directed to a useful embodiment, a claim must define the inventive element or combination of elements necessary to enable the proper operation of the invention for its intended purposes.[32] A feature that is required to allow the invention to work, the presence of which is understood by the person skilled in the art as being implicit, need not be explicitly defined.[33]

12.04.01 Controllability and reproducibility

To be considered to have utility an invention must be controllable and be reliably reproducible;[34] the desired result must inevitably follow when the invention is put into practice and may not be left up to chance. It is to be noted that the idea that "the desired result must inevitably follow" can refer to an accepted degree of success of a particular repetitive mass production method. For example, if a method is known and well recognized in a particular art as having a particular ratio of success or a certain percentage of rejects, the desired result inevitably follows if the method's ratio of success is inside such generally accepted parameters or if the method produces a percentage of rejects that is within these known parameters.

Inventions which are arrived at by chance and which cannot be reliably reproduced lack utility.[35] An invention that relies upon the judgment or reasoning of an operator is considered to lack reproducibility and thus, lacks utility.[36] Certain mental steps involving the ascertaining and sensing facilities have precise and predictable results, and do not of themselves cause the art or process that relies on them to lack utility. Whenever a person is called upon to perform a subjective judgement, however, the result will invariably be subject to factors such as intuition, creativity, conjecture and approximation, and the result will not be objectively controllable or reproducible. This lack of control and reproducibility is amplified if the subjective judgement calls into play a person's system of values, beliefs, interests or preferences.

12.04.02 Demonstration or sound prediction

The utility of an invention must be established as of the filing date of the patent, either by demonstration or sound prediction.[37] Where an examiner reviewing an application has reasonable grounds to believe that the application does not comply with the utility requirement of section 2 of the *Patent Act* and in response the applicant provides data to demonstrate utility, the data must show that the utility of the invention was demonstrated as of the filing date. "Unless the inventor is in a position to establish utility as of the time the patent is applied for, on the basis of either demonstration or sound prediction, the Commissioner is "by law" required to refuse the patent."[38] "Utility and sound prediction are questions of fact and must obviously be supported by evidence."[39]

Where the utility of an invention is to be established by demonstration, the demonstration must have occurred as of the filing date but need not have been included in the description.[40] Information establishing the demonstrated utility as of the filing date may be provided after the filing date by the applicant by way of affidavit.

Where an applicant is called upon to establish utility and proposes to demonstrate that their invention had utility as of the filing date, this demonstrated utility should be established by experimentation and testing of all embodiments of the invention or of all members of a genus claimed, for example, and cannot rely on literal assertions that the claimed invention has utility.

When an applicant is not in a position to demonstrate the utility of the invention, a sound prediction must be relied upon to establish utility. Soundly predicted utility pertains to embodiments of the invention that have not been *demonstrated* to have utility, but for which an appropriate factual basis exists upon which this utility, across the full scope of the claimed invention, can be predicted. That is, the utility need not have been demonstrated at the time of filing the patent, but the scientific rationale underlying the utility must have been established through a sound prediction at the time of filing.

It bears mentioning that the doctrine of sound prediction is of general applicability in every field for which patent protection may be sought and has, for example been applied in the mechanical arts.[41]

12.04.03 Requirements for sound prediction

A sound prediction analysis must consider the following three components:

(1) there must be a factual basis for the prediction;

(2) the inventor must have at the date of the patent application an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis; and

(3) there must be proper disclosure.[42]

The factual basis generally comprises the facts regarding the invention that are provided by the applicant in the description and drawings, relevant scientific principles, and information pulled from the common general knowledge of the person skilled in the art. The sound line of reasoning can be thought of as the analysis that sets out how the applicant logically bridges the gap between the factual basis and the purported utility of the invention.

The relevant date for determining whether the prediction is "sound" is the filing date of the application.[43]

It is important to keep in mind that a "sound prediction" by its very definition does not imply certainty; however a sound prediction is not to be diluted to a lucky guess or mere speculation.[44] Consequently, in assessing whether or not utility has been established via a sound prediction the emphasis is appropriately placed on the term "sound", and the question at hand is whether a prediction is "sound" or "speculative". *In Monsanto Co. v. Commissioner of Patents*, Pigeon J. adopted the following terms to express this lack of certainty: "[i]f it is possible for the patentee to make a sound prediction and to frame a claim which does not go beyond the limits within which the prediction remains sound, then he is entitled to do so. Of course, in so doing he takes the risk that a defendant may be able to show that his prediction is unsound or that some bodies falling within the words he has used have no utility or [...] that some promise he has made in his specification is false in a material respect".[45]

12.04.03*a* Factual basis

Evaluating what will be a sufficient factual basis for a sound prediction must be conducted on a case-by-case basis and will depend on such factors as:

(i) the scope of the claims;
(ii) the state of the art;
(iii) the nature of the invention and its predictability; and
(iv) the extent to which the applicant has explored the area claimed, for example by conducting experiments which provide a factual basis for the purported utility.

A factual basis does not by necessity mean experimental data[46] and though it may be provided by way of examples there is no absolute requirement that this be so. The factual basis could be found in scientifically accepted laws or principles, in data forming part of the state of the art and referred to in the description, or in information that is considered to be common general knowledge of the person skilled in the art.

The term "factual basis" implies support and proof. As mentioned in 12.04.03, "[u]tility and sound prediction are questions of fact and must obviously be supported by evidence".[47] Simple, unsubstantiated statements in the description suggesting that the invention will work are not considered to be factual. Similarly, while an applicant can include "prophetic examples" in their application, they have no value in providing a factual basis for a sound prediction. A prophetic example is by definition a statement of what might be, rather than what is, and therefore is not factual.

12.04.03*b* Sound line of reasoning

The sound line of reasoning connects the factual basis to the purported utility of the invention. The person skilled in the art must be able to understand how the sound line of reasoning links the factual basis to the purported utility of the invention.

12.04.03*c* Proper disclosure of the sound prediction

For there to be a proper disclosure of the sound prediction, the description must provide sufficient information such that a skilled person in the art, in light of their CGK, would understand the basis of the sound prediction and be able to predict that the entire scope of the claimed invention would work once reduced to practice.[48]

With respect to what needs to be disclosed to meet the third requirement of the sound prediction analysis, it is the factual basis and the sound line of reasoning that must be disclosed.[49] The extent to which the factual basis and sound line of reasoning must be described in the original description must be evaluated on a case-by-case basis. Elements of either the factual basis or the sound line of reasoning that can be found in scientifically accepted laws or principles, or which would be self-evident to a person of skill in the art in view of the common general knowledge will not, as a general rule, need to be disclosed in the specification. Information that forms part of the state of the art could, depending on the specific circumstances, be properly disclosed merely by referring to the document in which it is set out. Where such documents are referred to they must be properly identified.[50]

Where a sound prediction relies on additional information that is not publicly available, such information must be included in the description[51] at the time of filing. In contrast with evidence that *demonstrates* utility, an applicant cannot provide evidence after the filing date to properly disclose a *sound prediction*, even if the evidence was generated before the filing date. Explanations provided during prosecution as to the nature of the sound line of reasoning can only be considered to the extent that they explain why a person skilled in the art would have appreciated the sound line of reasoning on the basis of the description as filed and their common general knowledge.

Since the disclosure is directed to a person skilled in the art, the disclosure must allow that person to make a sound prediction. It is not enough for the description to disclose information that allows for a sound prediction only when interpreted in view of information not available to the public (e.g. proprietary knowledge possessed by the applicants only), or only when interpreted by an expert having a level of knowledge beyond that expected of the person skilled in the art.

Although an applicant is generally not required to provide a theory of how an invention works, if the utility of the invention is predicated on a sound prediction, and the line of reasoning depends on an understanding of the theory as to why the invention works, it may not be possible to properly express the line of reasoning unless this theory is disclosed.

It is important to note that the disclosure requirement within the sound prediction analysis and the sufficiency of disclosure requirement are distinct and separable requirements.[52] The disclosure requirement within sound prediction analysis is tied to the requirement that an invention have utility as set out in section 2 of the *Patent Act;* it does not pertain to the sufficiency of disclosure requirement set out in subsection 27(3) of the *Patent Act*. [See chapter 9 for a discussion of sufficiency.]

Example 1:

An application describes the use of a solution comprising cells and a biocompatible, cross-linkable hydrogel-forming polymer to produce, when injected into a patient, a tissue-equivalent (which comprises a three-dimensional (3D) open-lattice hydrogel with cells dispersed therein). The description states that any biocompatible, cross-linkable hydrogel-forming polymer is suitable to create the tissue-equivalent. Also disclosed is detailed information concerning the preferred types of biocompatible, cross-linkable hydrogel-forming polymers that can be used and the specific structural features of each of these types of polymers that make them suitable for use. In particular, the description demonstrates that a tissue-equivalent is successfully formed using a *calcium alginate* polymer and osteoblast cells.

Claims:

1. A use of a cell-polymeric solution for injecting a cell suspension into an animal under conditions which cross-link the cell-polymeric solution within the animal to form a three-dimensional open-lattice structure having cells dispersed therein, the solution comprising a biocompatible hydrogel-forming biopolymer which can be cross-linked via covalent, ionic, or hydrogen bonds to create a three-dimensional open-lattice hydrogel which entraps water molecules to form a gel, mixed with osteoblast cells.

2. The use of claim 1 wherein the biocompatible hydrogel-forming biopolymer is calcium alginate.

Analysis: claim 1 encompasses the use of any biocompatible cross-linkable hydrogel-forming biopolymer to create a three-dimensional open-lattice hydrogel for the delivery of osteoblast cells into an animal, while claim 2 is limited to the use of calcium alginate as the biopolymer. Where the utility of an invention is called into question, the applicant must be in a position to show that they had either demonstrated or soundly predicted the utility of the invention as of the filing date. In this case, the examiner questions the utility of the invention and notes that the description demonstrates that calcium alginate is a suitable biopolymer for the creation of the desired open-lattice hydrogel. As such, the utility of claim 2 is considered to be established by demonstration and is compliant with section 2 of the *Patent Act*. What is not demonstrated with respect to claim 1, however, is the use of other suitable polymers, other than alginate. In view of this, it is apparent that the utility over the full scope of claim 1 has not been demonstrated and must, therefore, be established on the basis of a sound prediction.

In order for the prediction to be "sound", there must be a factual basis for the prediction, an articulable and sound line of reasoning from which the desired result can be inferred from the factual basis, and there must be a proper disclosure of the factual basis and sound line of reasoning.

The factual basis disclosed in the description includes the fact that alginate, which is a biocompatible polymer that can be cross-linked to form a 3D open-lattice hydrogel, was successfully used to achieve the desired result (i.e., creating a tissue-equivalent). Further, in this case it is part of the common general knowledge of a person skilled in the art that the open-lattice hydrogel-forming ability is not unique to the alginate polymer as it is a property shared by many other known biopolymers that are capable of cross-linking through covalent, ionic, or hydrogen bonds.

The line of reasoning is articulated to be that the presence of specific structural features relating to biocompatibility and cross-linkability are required in a polymer in order to produce a 3D open-lattice hydrogel. Given the fact that alginate has these structural features and forms the tissue-equivalent, the applicant states that other polymers having the same specific structural features would also produce a 3D open-lattice hydrogel and deliver the same result. In view of the factual basis, the line of reasoning is considered to be sound and both the first and second requirements of the sound prediction analysis have been satisfied. Given that elements of both the factual basis and the sound line of reasoning that were not CGK to the POSITA were disclosed in the description at the time of filing, the requirement for proper disclosure is also met. Therefore, claim 1 satisfies the utility requirement of section 2 of the *Patent Act*.

Example 2:

An application describes a method of controlling weeds in a wheat field wherein wheat plants comprising a mutated acetohydroxyacid synthase (AHAS) gene have increased tolerance to imazapyr, an imidazolinone herbicide. The description subsequently states that any mutation in Domain A of the AHAS gene in wheat will confer imazapyr resistance to the wheat. This mutation in wheat allows for weeds to be selectively targeted when the imazapyr herbicide is applied to a field containing both weeds and the mutant wheat plants. Both the wild-type AHAS gene (SEQ ID NO:1) and a mutant AHAS gene having a single nucleotide substitution in Domain A (SEQ ID NO: 2) are disclosed. The description demonstrates that wheat plants comprising the mutant gene of SEQ ID NO:2 are resistant to the imazapyr herbicide, while the wheat plants comprising the unmodified wild-type AHAS gene (SEQ ID NO:1) show susceptibility to the herbicide. The application makes no mention of any other mutations in Domain A of the AHAS gene, nor does it include any information regarding why the applicant believes that *any* such mutation would lead to the increased tolerance to the imazapyr herbicide.

Claim:

1. A method of controlling weeds in a field, the method comprising:
    - (a) growing in a field a wheat plant having increased tolerance to imazapyr herbicide and;
    - (b) contacting the wheat plant and weeds in the field with an effective amount of the imazapyr herbicide; wherein the wheat plant comprises an AHAS gene which comprises a mutation in Domain A.

Analysis: the application claims that a method of controlling weeds in a wheat field using the imazapyr herbicide will be effective where wheat plants in the treated field comprise *any* mutation in Domain A of the AHAS gene. The description demonstrates that one particular mutation in Domain A of the gene, as depicted in SEQ ID NO:2, successfully provides resistance to wheat plants when exposed to imazapyr. What has not been demonstrated, but which is covered in the claim, is that any and all possible mutations in Domain A of AHAS would result in the utility of imazapyr herbicide resistance. In view of this, it is apparent that the utility has not been demonstrated over the full scope of the claim and since the examiner questions the utility, it must be established on the basis of a sound prediction.

The factual basis disclosed is that the AHAS gene is associated with the imazapyr herbicide and that a specific Domain A mutation, as defined in SEQ ID NO:2, confers increased tolerance to said herbicide. These facts alone, however, are not enough to soundly predict the utility of all possible Domain A mutations. The person skilled in the art, in light of their CGK and the information provided in the description, would recognize the complexity and unpredictability of gene expression, and as such, would not be led to extrapolate that the specific Domain A mutation of SEQ ID NO:2 is a reasonable predictor that all possible mutations in Domain A would confer a similar tolerance. As such, there is no articulable and sound line of reasoning.

Therefore, in the absence of an articulate sound line of reasoning, the skilled person could not soundly predict that any and all mutations in Domain A of the AHAS gene would have the disclosed utility. As such, the claim is defective under section 2 of the *Patent Act* because the utility has not been established on the basis of either demonstration or sound prediction over the full scope of the claim.

12.05 Office actions on utility November 2017

Where there is evidence of inutility in respect of the subject-matter claimed, or where an examiner questions the purported utility and determines that the applicant has not established that utility, either through demonstration or sound prediction, a defect will be identified under section 2 of the *Patent Act*. A defect may also be identified when the description fails to demonstrate or soundly predict the utility over the entire scope of a claim.

Where an examiner determines that utility is not established by a sound prediction, the examiner must include supporting arguments which detail how the defect is related to the three step test of sound prediction as set out in section 12.04.03.

It should be noted that evidence of inutility can be provided at any time and there is no requirement that such evidence existed at the time the application was filed.

As mentioned above, care must be taken to ensure that the disclosure requirement of sound prediction is not confused with the sufficiency requirement under subsection 27(3) of the *Patent Act*. An examiner may determine that there is a separate and independent defect under subsection 27(3) of the *Patent Act* if the description fails to sufficiently disclose the invention, or if the person skilled in the art could not put it into practice without undue experimentation or without exercising inventive skill. Where both defects are presented in an examiner's report the report must clearly identify both defects and provide separate supporting arguments for each.

On occasion, an examiner may be presented with an alleged invention that is contrary to known scientific principles. Unless the proper operation of such an invention can be established by demonstration (and the applicant can show that it was, in fact, demonstrated at the time of filing), the claims defining it are identified as defective under section 2 of the *Patent Act*.

Endnotes

[1] *Shell Oil v. Commissioner of Patents* [(1982), 67 C.P.R. (2nd), 1 (S.C.C.)] at pages 10-11

[2] *Canadian Gypsum Co. Ltd. v. Gypsum, Lime & Alabastine, Canada, Ltd.* [1931] Ex.C.R. 180

[3] *Tennessee Eastman v. Commissioner of Patents* [(1972), 8 C.P.R. (2nd), 202 (S.C.C.)]

[4] *Shell Oil v. Commissioner of Patents* [(1982), 67 C.P.R. (2nd), 1 (S.C.C.)] at pages 10-11

[5] *Commissioner of Patents v. Ciba Ltd.* [(1959), 30 C.P.R. (1st), 135 (S.C.C.)] at page 141; aff'g [(1957), 27 C.P.R. (1st), 82 (Ex.Ct.)]

[6] "machine *noun*" *The Oxford Dictionary of English (revised edition)*, Oxford University Press 2005; "machine" *The Concise Oxford Dictionary of Mathematics*, Oxford University Press 2005

[7] *Harvard College v. Canada (Commissioner of Patents)* [2002] S.C.C. 76; [(2002), 21 C.P.R. (4th), 417 (S.C.C.)] at paragraph 159. The court relied on the definitions of the term in the Oxford English Dictionary and the Grand Robert de la langue française

[8] *Harvard College v. Canada (Commissioner of Patents) [2002] S.C.C. 76; [(2002), 21 C.P.R. (4th), 417 (S.C.C.)]* at paragraphs 157-163

[9] Canada (Attorney General) v. Amazon.com, Inc. 2011 FCA 328 at paragraph 66

[10] *Shell Oil v. Commissioner of Patents* [(1982), 67 C.P.R. (2nd), 1 (S.C.C.)] at page 14

[11] *Riello Canada, Inc. v. Lambert* [(1986), 9 C.P.R. (3rd), 324 (F.C.T.D.)] citing at pages 335 and 336 *Reynolds v. Herbert Smith & Co., Ltd.* [(1902), 20 R.P.C., 123 (Ch.D.)]

[12] *Harvard College v. Canada (Commissioner of Patents)* [2002] S.C.C. 76; [(2002), 21 C.P.R. (4th), 417 (S.C.C.)] at paragraph 158

[13] *Schlumberger Canada Ltd. V. Commissioner of Patents* [(1981), 56 C.P.R. (2nd) 204 (F.C.A.)] at page 206

[14] *Harvard College v. Canada (Commissioner of Patents) [2002] S.C.C. 76; [(2002), 21 C.P.R. (4th), 417 (S.C.C.)]* at paragraphs 159 to 163

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[15] *Re Application No. 44,282 of Leubs* (1971) C.D. 80 (relating to wood panels wherein the novelty lay in particular inscribed designs); *Re Application No. 245,995* for a Townhouse building design [(1979) C.D. 605, 53 C.P.R. (2nd), 211 (P.A.B.)] (relating to architectural plans or designs); *Re Application 040,799 of Cowan* (1971) C.D. 79.; *Lawson v. Commissioner of Patents* [(1970), 62 C.P.R. (1st), 101 (Ex. Ct.)]

[16] *Re Application No. 565,417 of Pilot Ink Co.* [(1997) C.D. 1224, 86 C.P.R. (3rd), 66 (P.A.B.)]

[17] *Re Application No. 996,098 of Boussac* (1973) C.D. 143

[18] *Re Dixon Application No. 159, 204* [(1978 C.D. 493, 60 C.P.R. (2nd), 105 (P.A.B.)], the Commissioner cited with approval the conclusions reached in the UK cases *Cooper's Application* [(1902) 19 R.P.C. 53] and *Fishburn's Application* [(1940) 57 R.P.C. 245]

[19] *Re Application No. 003,389 of N.V. Organon* [(1973) C.D. 144, 15 C.P.R. (2nd), 253 (P.A.B)] at page 258

[20] *Canada (Attorney General) v. Amazon.com, Inc.* 2011 FCA 328 at paragraph 58

[21] *Lawson v. Commissioner of Patents* [(1970), 62 C.P.R. (1st), 101 (Ex. Ct.)] at page 115, in respect of "plans"

[22] *Schlumberger Canada Ltd. V. Commissioner of Patents* [(1981), 56 C.P.R. (2nd) 204 (F.C.A.)] at page 206

[23] *Re Application No. 040,799 of Cowan* (1971) C.D. 79

[24] *AstraZeneca Canada Inc. v. Apotex Inc.*, 2017 SCC 36 at paragraph 57

[25] AstraZeneca (supra at 25) at paragraph 52

[26] AstraZeneca (supra at 25) at paragraph 56, citing *Re Application of Abitibi Co.* (1982), 62 C.P.R. (2d) 81, (Patent Appeal Board and Commissioner of Patents), at p. 91

[27] AstraZeneca (supra at 25) at paragraph 54

[28] AstraZeneca (supra at 25) at paragraph 53

[29] AstraZeneca (supra at 25) at paragraph 55

[30] *Teva Canada Ltd. v. Pfizer Canada Inc.* 2012 SCC 60 at paragraph 40; AstraZeneca (supra at ??) at paragraph 58

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[31] Apotex Inc. v. Wellcome Foundation Ltd. 2002 SCC 77 at paragraph 46; AstraZeneca (supra at ??) at paragraphs 55-56

[32] *Feherguard Products Ltd. v. Rocky's of BC Leisure Ltd.* [(1995), 60 C.P.R. (3rd), 512 (F.C.A.)] at pages 516 to 517.

[33] *Metalliflex Ltd. v. Rodi & Wienenberger AG* [1961] SCR 117 & [(1960), 35 C.P.R. (1st), 49 (S.C.C.)] at pages 53-54

[34] Organon (supra at 18)

[35] *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)* [(1989), 25 C.P.R. (3rd), 257 (S.C.C.)] at page 270.

[36] *Re Application for Patent* Containing Claims that Read on Mental Steps [(1972) C.D. XXX, 23 C.P.R. (2nd), 93]; *Re Application 269,230 of Itek Corporation* (1981) C.D. 896

[37] *Apotex Inc. v. Wellcome Foundation Ltd.* 2002 SCC 77 at paragraph 46

[38] *Apotex Inc. v. Wellcome Foundation Ltd.* 2002 SCC 77 at paragraph 46

[39] *Pfizer Canada Inc. v. Apotex Inc.* 2007 FC 26 at paragraph 70; aff'd 2007 FCA 195

[40] *Pfizer Canada Inc. v. Novopharm Limited* 2009 FC 638 at paragraph 82, aff'd 2010 FCA 242 at paragraph 82, aff'd 2012 SCC 60 at paragraph 40

[41] *Bell Helicopter Textron Canada Ltd. v. Eurocopter* 2013 FCA 219 at paragraphs 48-51 and 135-162

[42] *Apotex Inc. v. Wellcome Foundation Ltd.* 2002 SCC 77 at paragraph 70

[43] *Aventis Pharma Inc. v. Apotex Inc.* 2005 FC 1283, 43 C.P.R. (4th) 161 at paragraph 164; aff'd on this point 2006 FCA 64, 46 C.P.R. (4th) at paragraph 30; Apotex (supra at 25) at paragraph 46

[44] *Apotex Inc. v. Wellcome Foundation Ltd.* 2002 SCC 77 at paragraph 69

[45] *Monsanto Co. v. Commissioner of Patents* [(1979), 42 C.P.R. (2nd), 161 (S.C.C.)] at page 176, citing *Olin Mathieson Chemical Corp. et al. v. Biorex Laboratories Ltd. et al.* [1970] R.P.C. 157

[46] *Pfizer Canada Inc. v. Canada (Minister of Health)* 2007 FCA 209 at paragraph 152

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[47] *Pfizer Canada Inc. v. Apotex Inc.* 2007 FC 26 at paragraph 70; aff'd 2007 FCA 195

[48] *Eli Lilly Canada Inc. V. Apotex Inc.* 2009 FCA 97 at paragraphs 10 to 18; *Eli Lilly Canada Inc. v. Novopharm Limited* 2009 FC 235 at paragraph 101; *Servier Canada v. Apotex Inc.* 2008 FC 825 at paragraph 99

[49] *Apotex Inc. v. Pfizer Canada Inc.* 2011 FCA 236 at paragraph 52

[50] *Eli Lilly Canada Inc. v. Apotex Inc.* 2008 FC 142 at paragraphs 163-164; *Eli Lilly v. Apotex* (supra at 57) at paragraph 12

[51] *Eli Lilly v. Apotex Inc.* 2009 FCA 97 at paragraph 18; this requirement extends equally to any factual basis needed to support a sound prediction of an advantage possessed by a selection from a broader group, see *Pfizer Canada Inc. v. Canada (Minister of Health)* 2008 FC 500 at paragraph 97 and *GlaxoSmithKline Inc. v. Pharamscience Inc.* 2008 FC 593 at paragraph 71

[52] *Eli Lilly Canada Inc. v. Novopharm Ltd.* 2010 FCA 197 at paragraph 120

Chapter 13
Examination of Applications

13.01 Scope of this chapter

June 2015

This chapter covers the examination of regularly filed and national phase applications. Information regarding the examination of International applications can be found in chapter 22.

13.02 Request for examination

June 2015

Under the *Patent Act*, an application is not examined automatically. Rather, Canada operates on a system of deferred examination, wherein an application is only examined upon request.

In accordance with subsection 35(1) of the *Patent Act*, a request for examination may be made by any person, as long as it is in the prescribed manner and accompanied by the necessary fee (set out in item 3 of Schedule II of the *Patent Rules*). The Commissioner of Patents may also, under subsection 35(2) of the *Patent Act*, require an applicant to request examination of an application.

If a request for examination is made by a third party, the Office will inform the applicant of this fact.

Section 95 of the *Patent Rules* states that the following information must be included with a request for examination:

> (*a*) *the name and address of the person making the request;*
> (*b*) *if the person making the request is not the applicant, the name of the applicant;*
> (*c*) *information, such as the application number, sufficient to identify the application.*

According to section 96 of the *Patent Rules,* a request for examination must be made before the expiry of the five-year period after the filing date of the application or, in the case of a divisional application, the later of this five-year period and the six-month period after the date on which the divisional application is actually filed.

If a request for examination is not made or the request for examination fee is not paid within the prescribed period or within the time specified in a notice sent by the Commissioner under subsection 35(2) of the *Patent Act*, the application will be considered abandoned in accordance with paragraph 73(1)(*d*) or 73(1)(*e*) of the *Patent Act*, respectively [see also chapter 20 of this manual].

13.03 Advanced examination

June 2015

Applications are generally examined sequentially according to the date on which the request for examination was made.[1] There are however mechanisms by which an application may be advanced out of routine order: "special order" advanced examination; advanced examination of applications related to green technology; and the Patent Prosecution Highway.

13.03.01 Advanced examination (special order)

Under subsection 28(1) of the *Patent Rules*, the Commissioner of Patents shall advance an application for examination out of its routine order on the request of any person who pays the fee set out in item 4 of Schedule II of the *Patent Rules*, where the Commissioner determines that failure to advance the application is likely to prejudice that person's rights. Applications that are subject to advanced examination are commonly referred to as "special order" applications.

In accordance with subsection 28(1) of the *Patent Rules*, a request for advanced examination (special order) can only be granted if the application in question is open to public inspection under section 10 of the *Patent Act* and a request for examination has been made pursuant to subsection 35(1) of the *Patent Act*.

Although a third party may request advanced examination of an application, subsection 10(2) of the *Patent Act* specifies that only the applicant may request that an application be opened to public inspection before the expiry of the confidentiality period. A request to advance examination made by a third party will only be held for consideration if the application is scheduled to be opened to public inspection within three months of the request. A decision to advance the examination of the application out of its routine order will only be made once the application is open to public inspection. If the request for advanced examination is submitted by a third party more than three months before the application is scheduled to be opened to public inspection, the request will be refused. The Office will inform the applicant of the request by letter.

A request to advance examination will not be considered if the application in respect of which the request was made is incomplete [see Chapter 5 for completion requirements].

Once an application is advanced out of its routine order, this order will generally apply for the duration of prosecution; however, subsection 28(2) of the *Patent Rules* specifies that an application will be returned to its routine order if:

> *(a) the Commissioner extends, under subsection 26(1), the time fixed by the Patent Rules or by the Commissioner under the Patent Act for doing anything in respect of the application; or*
>
> *(b) the application is deemed to be abandoned under subsection 73(1) of the Patent Act whether or not it is reinstated under subsection 73(3) of the Patent Act.*

A person who requested advanced examination can also request that advanced examination cease, in which case the application will be examined in its regular order. The fee for requesting advanced examination is not refundable under section 4 of the *Patent Rules*.

13.03.02 Applications related to green technology

Under paragraph 28(1)(*b*) of the *Patent Rules,* examination of a patent application which is related to green technology can be advanced out of routine order upon request. The applicant must submit a declaration stating that the application relates to technology "the commercialization of which would help to resolve or mitigate environmental impacts or conserve the natural environment and resources." No additional fee is required.

In accordance with subsection 28(1) of the *Patent Rules* a request for advanced examination for an application related to green technology can only be granted if the application in question is open to public inspection under section 10 of the *Patent Act* and a request for examination has been made pursuant to subsection 35(1) of the *Patent Act*.

13.03.03 The Patent Prosecution Highway (PPH)

Examination of applications having family members with claims that are granted or determined to be allowable in other jurisdictions may be eligible to be advanced out of routine order via the Patent Prosecution Highway (PPH). In order for an application to qualify for the PPH, the PPH request must be received before examination has begun and the application in question must be open to public inspection. No additional fee is required.

13.04 Examination
April 2018

The purpose of examination is, at each stage, to perform a thorough analysis of the patent application to determine whether it complies with the requirements of the *Patent Act* and *Patent Rules*. After receiving a request for examination an examiner will analyse the application taking into consideration the originally filed application and any amendments that have been received in the Patent Office.

After having performed this analysis, the examiner will either allow the application in accordance with subsection 30(1) of the *Patent Rules* or issue a report detailing the application's defects in accordance with subsection 30(2) of the *Patent Rules*. Where a report is to be issued, it should be as comprehensive as possible, to enable the applicant to make informed decisions regarding the continued prosecution of their application and, if possible, to place the application in a condition for allowance [see section 13.11]. In some cases, the examiner may initiate a telephone interview, in lieu of issuing a report, in accordance with section 1.08.02 of this manual, where such an interview may advance the prosecution expeditiously.

Note that an application for which examination has been requested may be examined prior to being laid open to public inspection under section 10 of the *Patent Act*, but an examiner will not approve an application for allowance until it has been laid open.

13.04.01 Examination of the abstract, description and drawings

A detailed discussion regarding examination of the abstract, description and drawings can be found in chapters 8, 9 and 10 of this manual, respectively.

13.05 Examination of the claims using purposive construction
June 2015

In *Canada (Attorney General) v Amazon.com Inc*, the Federal Court of Appeal observed that, during examination, Supreme Court jurisprudence "requires the Commissioner's identification of the actual invention to be grounded in a purposive construction of the patent claims".[2]

The application of the principles of purposive construction to the examination of a patent application must take into account the role of the patent examiner and the purpose and context of examination..[3]

In *Free World Trust* and *Whirlpool*, the Supreme Court outlined that purposive construction is performed by the court to objectively determine what the person skilled in the art would, as of the date of publication of the patent application and on the basis of the particular words or phrases used in the claim, have understood the applicant to have intended to be the scope of protection sought for the disclosed invention..[4]

Once a claim has been purposively construed, that construction is used to determine whether the claim complies with the *Patent Act* and *Patent Rules*. Where there is no disagreement as to the construction of a claim, the examiner may choose not to provide the detailed purposive construction analysis in a report.

13.05.01 Steps of purposive construction

When examining a claim, an examiner must read the claim in an informed and purposive way. Prior to construing a claim an examiner will:

1) Identify the person of ordinary skill in the art [see chapter 15]; and

2) Identify the relevant common general knowledge of the person of ordinary skill in the art at the time of publication [see chapter 15].

The above steps provide the context in which the claim is to be read. Once the context is determined the examiner will:

3) Identify the problem addressed by the application and its solution as contemplated by the inventor [see 13.05.02b]; and

4) Determine the meaning of the terms used in the claim and identify the elements of the claim that are essential to solve the identified problem [see 13.05.02c].

13.05.02 Considerations for claim construction

Claim construction during examination therefore requires an examiner to interpret each claim in a structured manner whereby the examiner will:

13.05.02*a* Use a fair, balanced and informed approach

The specification as a whole is addressed to the person skilled in the art and, as such, provides the context in which the claim should be read and informs the meaning of the terms recited in the claim and the nature of the invention..[5] Upon a purposive construction the terms of a claim will be given specific technical meanings in light of the common general knowledge of the person skilled in the art..[6] Thus, in order to arrive at a fair, balanced and informed understanding of the subject-matter of a claim, it is critical that a purposive construction of the claim be performed considering the specification as a whole as read through the eyes of the person skilled in the art, against the background of the common general knowledge in the field or fields relevant to the invention at the time the application became available to the public.

During examination, the necessary foundation of knowledge for performing a purposive construction of the claims is found in submissions from the applicant and the knowledge of an appropriately experienced examiner..[7]

13.05.02*b* Identify the problem and solution

The purpose of the *Patent Act* is to provide exclusive rights to an inventor for a new and useful invention in exchange for a disclosure that allows the public to use or operate the invention as contemplated by the inventor. Thus, recognizing that a patentable invention is an inventive solution to a practical problem[8], it follows that an invention must be disclosed (and ultimately claimed) so as to provide the person skilled in the art with an operable solution.

The identification of the problem and the solution provided by the invention informs the purposive construction of the claims..[9]

The identification of the problem faced by the inventor is guided by the examiner's understanding of the common general knowledge in the art and by the teachings of the description.

The common general knowledge in the art provides the baseline of information to which the description is expected to add. The person skilled in the art will read the specification in the expectation that it sets out something beyond the commonly known solutions to commonly known problems.

It must be borne in mind that the applicant is not required to explicitly state the problem and solution. Paragraph 80(1)(*d*) of the *Patent Rules* makes this clear, stating that the description shall:

> *describe the invention in terms that allow the understanding of the technical problem, even if not expressly stated as such, and its solution.*

Consequently, the identification of the problem and its solution may be an integrated exercise, *i.e.* the manner in which the solution is described can help inform the problem, and vice versa. For example, a significant focus in the description on certain details of the solution may assist in the identification of the problem, while a relative absence of emphasis on certain aspects of the solution may likewise suggest the problem lay elsewhere. Where the applicant is explicit as to the nature of the problem, examination should generally proceed accordingly unless doing so would be unreasonable on an informed reading of the application in light of the common general knowledge.

The examiner will give consideration to what the inventor states about the background of the invention, the "objects of the invention", any specific problems, needs, limitations or disadvantages known in the art or discovered by the inventor, etc. in identifying the problem faced by the inventor.

While claim construction during examination must remain anchored in the language of the claims, it "cannot be determined solely on the basis of a literal reading" of the claims..[10] A properly informed purposive construction must consider the application as a whole.

Not only must one not lose sight of the fact that the claims must be interpreted in light of the description, a claim-based analysis "does not mean that the Commissioner cannot ask or determine what the inventor has actually invented, or what the inventor claims to have invented. On the contrary, these are relevant and necessary questions in a number of contexts, including novelty, obviousness, and patentable subject matter"..[11] This is consistent with the recognition in *Free World Trust* of the need to avoid "the pitfalls of language" so as to ensure the inventor receives "protection for that which he has actually in good faith invented"..[12]

13.05.02*c* Determine which elements of the claim solve the identified problem

One aspect of purposive construction is the identification of the essential elements of the claim. The identification of the essential elements of a claim cannot be performed without having first properly identified the proposed solution to the disclosed problem. Without having first considered the problem and solution, the identification of essential elements would be circular - it would begin and end with the language of the claim, contrary to *Free World Trust* which recognizes that elements can be found to be non-essential if at the date of publication of the patent, the skilled addressee would have appreciated that a particular element could be substituted or omitted without affecting the working of the invention..[13]

Ultimately, some element or combination of elements defined in the claim must provide the solution. One must, however, approach each claim with an understanding that not every element that has a material effect on the operation of a given embodiment is necessarily essential to the solution. Some elements of a claim define the context or the environment of a specific working embodiment, but do not actually change the nature of the solution to the problem..[14] .

Note that while the identification of the essential elements is performed in light of the knowledge of the art at the date of the publication of the patent specification,.[15] this does not mean that one can simply conclude that the essential elements of the invention are those that distinguish the claimed subject matter from the prior art..[16] That is, an element is not necessarily essential merely by the fact that is not found in the prior art. Likewise, an element cannot necessarily be deemed non-essential merely because it is part of the CGK. An element is essential if it is required to provide the solution to the problem, regardless of whether or not it is known.

Having identified the problem and solution, and defined the essential elements in the claims, an examiner may conclude that the claim either omits an essential element or includes non-essential elements.

Where it appears, having considered a claim in light of a fair reading of the description, that an element essential to the operation of the solution has not been defined in the claim, the claim may be defective for over breadth (*i.e.* lack of support) and/or for lack of utility.

In certain cases, an examiner may consider elements included in a claim of an application to be superfluous (non-essential) to the solution to a given problem. The mere presence of a superfluous limitation is not a defect as such, although the inclusion of such an element could render a claim defective (for example if its presence results in ambiguity).

It must be recognized that while the Office considers superfluous elements to be non-essential and not relevant to the determination of a claim's patentability during examination, if an applicant maintains such an element in the claim through to grant a court might later construe it to be essential when applying the "self-inflicted wound" factors of purposive construction as identified in *Free World Trust* and *Whirlpool*..[17]

An invention is an element or a combination of elements that provides a solution to a problem. Where a claim includes solutions to more than one problem it includes more than one invention..[18]

If a claim includes solutions to more than one problem, examination should focus on one solution to a problem in performing the purposive construction. The initial choice of solution should be guided by the description, selecting the solution given the greatest emphasis by the inventors. If it becomes necessary to consider a different solution, the analysis should be undertaken anew.

On occasion it may be the case that elements or sets of elements in a claim do not interact with each other to achieve a unitary result; this may reflect an "aggregation" rather than a combination..[19] A consideration of the problem and solution emphasized by the inventor in the description may assist the examiner to select only the element or set of elements that work together in the claim that provide the operable solution.

13.05.03 Examination once the claims have been construed

In most cases, an examiner reading a claim will automatically ascribe appropriate meanings to the terms of a claim in light of the teachings of the description and the examiner's technical expertise. It is not necessary to explain these conclusions in a report, unless it becomes apparent that there is some relevant disagreement between the examiner and the applicant as to the significance of certain terms. In such instances, it is only necessary to explicitly address the construction of the contested terms.

Similarly, in some cases it will be possible to conclude that a claim does not comply with the *Patent Act* or *Patent Rules* without explicitly determining whether a given element is or is not essential. A prior art document that discloses all the elements of a claim, for example, will anticipate the claimed subject-matter regardless of whether each element is essential or not. Here again, examiners are not required to detail in reports parts of their analysis that are not in issue.

Where an examiner's conclusions regarding a specific element are relevant to the identification of a perceived defect, the examiner should provide reasons to support their conclusions, e.g. emphasize the identified problem and solution and those elements essential to providing that solution.

Once the claims have been purposively construed, the essential elements can be analyzed to determine if they clearly define subject matter that complies with the *Patent Act* and *Patent Rules*. Specific requirements are discussed in the following chapters of the MOPOP:

Requirements for the clarity and form of the claims are covered in Chapter 11.

Subject matter and utility are covered in Chapter 12.

Novelty, obviousness and double patenting are covered in Chapter 15.

13.05.04 Examples of purposive construction

The following examples apply the guidance set out in this section to a determination of statutory subject matter.

Example 1:

An application is directed to a known skillet and a known spoon, where the skillet and spoon each incorporate a "specific identifier" in the form of a feature common to both products. The description indicates that it is known in the art to provide silicone grips on spoon handles to improve a user's grip on a spoon, and that it is known to include a silicone grip on a skillet handle to help insulate the handle. The application discloses that by incorporating the specific identifier in the handles of both products, a consumer is likely to buy the two products together due to the recognition of the specific identifier. The description indicates that the specific identifier has aesthetic appeal and that embodiments include a raised logo molded into the silicone and a specific striped pattern.

Claim:

1. A kit comprising:

    a) a spoon comprising a silicone-wrapped handle, wherein the silicone on the handle provides increased grip for a consumer, and wherein the silicone on the handle comprises a specific identifier;
    b) a skillet comprising a silicone-wrapped handle wherein the silicone provides insulation to the skillet handle, and wherein the silicone on the handle comprises the specific identifier;

    wherein the specific identifier comprises a raised logo.

Analysis:

Person of ordinary skill in the art (POSITA)

The POSITA is considered to be a person who is skilled in the design, production and manufacturing of cookware including the fields of metal working, forging, and plastic moulding. The POSITA is knowledgeable in the field of marketing.

Common general knowledge (CGK)

The description states that the use of silicone on spoon handles to improve the grip is

CGK and that the use of silicone on skillet handles is widely known as an insulator. Though an examiner could independently verify that the use of silicone on cookware is CGK, if an applicant explicitly states that certain knowledge is CGK the examiner may take such statements at face value. Methods of moulding silicone grips on cookware are well known. Methods of moulding logos and various patterns in silicone are common general knowledge.

The Problem

It is clear from the description that the problem the inventor has set out to solve is to influence a consumer to associate one product (the spoon) with another product (the skillet). Considering the statements made in the description and the common general knowledge, improving the grip on the spoon and insulating the skillet handle were not part of the problem that the inventor set out to solve.

The Solution

Though the applicant has claimed the silicone-wrapped handles and refers to the respective benefits that they confer to the spoon and skillet, these benefits are not material to solving the problem of leading a consumer to associate the two products together. The solution to the problem the applicant has set out is the provision of the specific identifier on both products.

What are the essential elements?

As the specific identifiers are the only elements of the claim that provide the solution to the problem outlined in the description, the specific identifiers are the only essential elements of the claim.

Is the claim statutory?

The specific identifiers are features having a purely intellectual or aesthetic significance which do not affect the practical functioning of the products. The examiner will therefore identify a defect under section 2 of the *Patent Act* since the only essential elements of the claim are the specific identifiers; the claims therefore do not define a statutory invention [see chapter 12 of the MOPOP for a discussion of statutory subject matter].

Example 2

An application is directed to a portable playpen for outdoor use. The description states that such playpens having no legs and flexible undersides are well known for use on slightly uneven terrain, such as in a park, as the flexible underside can conform to the terrain. The application discloses that the inventors set out to improve these playpens by adding a feature that would determine whether or not the playpen installation is stable and alert a parent if the installation is not stable. They have added several sensors at particularly chosen locations about the center of the playpen to gather data to calculate a stability factor. If the stability factor is below a predetermined threshold, an alarm attached to the playpen will sound.

Claim:

1. A method of determining the instability of an outdoor playpen comprising:

   providing a playpen with sensors adhered to positions X, Y and Z;

   measuring the vertical and horizontal load at each sensor;

   calculating an overall stability factor for the playpen using the data collected by the sensors; and

   sounding an alarm if the stability factor is below a predetermined threshold.

Analysis:

Person of ordinary skill in the art (POSITA)

The POSITA is knowledgeable in the field of children's furniture design, production and manufacturing, and in the fields of force measurement and electronics.

Common General Knowledge (CGK)

Outdoor playpens having flexible bottoms to allow them to conform to the contours of uneven terrain are well known. It is also known that various types of sensors can be incorporated into products to calculate various values.

The Problem

It is clear from the description that the problem the inventors wanted to solve was determining whether or not an outdoor playpen having a flexible bottom is stable when placed on uneven terrain.

The Solution

The solution as detailed in the description is to adhere sensors to locations X, Y and Z of the playpen, measure force data at each sensor, calculate a stability factor from the data, and sound an alarm when the stability factor is below a predetermined threshold.

What are the essential elements?

In order to solve the problem of determining whether or not an outdoor playpen is stable, the following elements of the claim are considered essential: adhering sensors to locations X, Y and Z of a playpen, measuring the force at each location, calculating the stability factor for the playpen using the data collected by the sensors, and sounding an alarm if the calculated stability factor is below a predetermined threshold.

Is the claim statutory?

Yes. The essential elements of adhering the sensors at locations X, Y and Z, measuring the force at each location and sounding the alarm are statutory elements that have a practical application.

Example 3, Scenario a):

An application is directed to a new board game in which game pieces are moved by players around the spaces on a 3-dimensional board depending on the number resulting from a roll of a dice. The board has a mechanized arm with a claw at one end that rotates around the board; depending on the orientation of the claw and the position of the piece, the claw will either knock over the player's piece or pick it up and place it in a different area of the board.

Claim:

1. A board game comprising:

   a 3-dimensional game board comprising a pattern of spaces;
   the board comprising a mechanized arm that is rotated around the centre of the board by a motor, said arm comprising a claw that can be positioned in two orientations, either horizontal or vertical; and

   a plurality of game pieces, wherein each piece comprises a means to interact with the claw when in the horizontal orientation thereby allowing said claw to pick up said piece.

Analysis:

Person of ordinary skill in the art (POSITA)

The POSITA is a designer and manufacturer of board games and is also knowledgeable in the field of mechanical engineering.

Common General Knowledge (CGK)

Board games in general are well known and the manufacture of 3-dimensional game pieces is CGK. Mechanical devices are also CGK.

The problem

The problem that has been identified in the description is the need to create a new board game.

The solution:

The solution as detailed in the description is the provision of a new board game that requires a plurality of game pieces and a 3-dimensional board comprising a mechanized arm and claw.
What are the essential elements?

The elements that are required to obtain the solution are the pieces and the 3-dimensional board comprising the mechanized arm and claw.

Is the claim statutory?

Yes. The essential elements, (the 3-dimensional board, the game pieces, and the mechanized arm and claw) provide a practical solution to the problem.

Example 3, Scenario b):

Ten years after the introduction of the board game of *Example 3, Scenario a)* into the market, the game has achieved commercial success and is well known world-wide. The inventor has filed a new application for an improved board game that now has additional instructions printed on the spaces of the board (e.g. move ahead three spaces, back two spaces, etc…). The improved board still comprises the original mechanized arm and claw.

Claim:

> A board game comprising:
> a 3-dimensional game board comprising a pattern of spaces;
> said board comprising a mechanized arm that is rotated around the centre of the board by a motor, said arm comprising a claw that can be positioned in two orientations, either horizontal or vertical;
> and a plurality of game pieces, wherein each piece comprises a means to

> interact with the claw when in the horizontal orientation thereby allowing said claw to pick up said piece;
> wherein 20% of the spaces comprise instructions on where to move a particular game piece.

Analysis:

Person of ordinary skill in the art (POSITA)

The POSITA is the same as that of *Example 3, Scenario a)* above.

Common General Knowledge (CGK)

Board games are CGK. The particular 3-dimensional board, pieces, mechanized arm and claw disclosed in the application are all CGK. The use of instructions on the spaces of a board game is CGK.

The problem

As detailed in the description, the problem is defined as finding an improved method of playing the game.

The solution:

The instructions printed onto 20% of the squares provide the solution to the identified problem.

What are the essential elements?

While the claim defines the game board, the pieces, and the mechanized arm and claw, these merely provide the context of the invention. They do not change the nature of the solution to the problem. The element that is essential to solve the identified problem is the inclusion of instructions on 20% of the spaces on the board.

Is the claim statutory?

No, the essential element is the inclusion of instructions that are printed on the spaces. The instructions are mere printed matter, which is not patentable subject matter.

Example 3 Scenario c):

Ten years after the introduction of the board game of *Example 3, Scenario a)* into the market, the game has achieved commercial success and is well known world-wide. The inventor has filed a new patent application for an improved game board having small hydraulic pistons at each corner of the board. The pistons are used to elevate and lower each corner of the board during the game so that the 3-dimensional characteristics change (i.e. the board is tilted) resulting in a changing interaction between the claw and the game pieces.

Claim:

> A board game comprising:
> a 3-dimensional game board comprising a pattern of spaces;
> the board comprising a mechanized arm that is rotated around the centre of the board by a motor said arm comprising a claw that can be positioned in two orientations, either horizontal or vertical;
> said board comprising a hydraulic piston at each corner to elevate or lower the corners thereby tilting the board;
> and a plurality of game pieces, wherein each piece comprises a means to interact with the claw when in the horizontal orientation thereby allowing said claw to pick up said piece.

Analysis:

Person of ordinary skill in the art (POSITA)

The POSITA is the same as that of *Example 3, Scenario a)* above.

Common General Knowledge (CGK)

Board games are CGK. The particular 3-dimensional board, pieces, mechanized arm and claw disclosed in the application are all CGK. Hydraulic pistons *per se* are CGK.

The problem

The problem outlined in the description is defined as finding an improved method of playing the game.

The solution

The solution to the problem is the inclusion of the hydraulic pistons at each corner of the game board so that the board can be tilted during game play.

What are the essential elements?

The board, pieces, arm and claw provide the context for the solution to the problem but are not essential elements that lead to the solution contemplated by the inventor. The essential elements are the hydraulic pistons which allow the tilting of the game board and which can cause the interaction between the claw and the game pieces to change.

Is the claim statutory?

Yes, the essential elements (the hydraulic pistons) provide a new practical application to the game board.

13.06 Search of the prior art

June 2015

Patentability must be assessed in view of the prior art, and it is therefore necessary for the relevant prior art to be identified. The prior art, broadly speaking, includes all information, in any form, made available to the public in Canada or elsewhere prior to the claim date[20], with a limited exception for information disclosed by the applicant or those obtaining information from the applicant (see paragraph 28.2(1)(a) of the *Patent Act*). In practice, however, the prior art relied on during examination generally comprises published patent documents, journal articles, textbooks, manuals and the like.

An application for patent in Canada may result from a national filing or from entry into the national phase of an international application filed in Canada or elsewhere under the Patent Cooperation Treaty (PCT).

The scope of the search of the prior art performed by a Canadian examiner at the national phase is determined in part by the extent to which relevant prior art has been identified in any earlier searches[21]. Further, examiners are not required to search claimed matter that is determined to be non-statutory, to lack practical utility or that is not supported by the application as filed (e.g. where new matter has been introduced contrary to subsection 38.2(2) of the *Patent Act*).

Where claimed matter is not required to be searched for any of the foregoing reasons, but it is evident from the specification as a whole that a claim to related subject-matter requiring a search could be made, a search should generally be performed on this related matter. By way of example, a claim to a method of medical treatment need not be searched, but if it is clear that a statutory claim could be made on related matter (such as a related use), this matter should be searched.

Where the claimed subject-matter has been the subject of a comprehensive international search by an International Searching Authority, a Canadian examiner will nevertheless perform at least a search of Canadian patent documents to identify documents relevant to double-patenting or to anticipation under paragraphs 28.2(1)(*c*) and 28.2(1)(*d*) of the *Patent Act*.

An examiner will typically consider available foreign search results to avoid unnecessary replication of work. Where the results of a foreign search are relied on in a report, the report should indicate which documents were identified in a foreign search.

Whenever the examiner deems it appropriate, a further search may be undertaken. This search need not be restricted to Canadian patent documents, and can be performed on any database or other search tool to which the examiner has access. Searches are generally limited by some combination of dates, keywords, and International Patent Classification (IPC) codes of relevance to the claimed matter.

In keeping with the purpose of an examiner's report, it is desirable for all relevant prior art to be identified at the time of the first report. Nevertheless, given the sheer quantity of prior art now available it must be acknowledged that in practice documents may be missed, or that at the early stages of examination the relevance of some documents may not be fully appreciated. It is also possible that, in view of amendments to the claims or arguments presented by the applicant, it becomes necessary to rely on additional prior art.

Where, for any reason, relevant prior art is identified during the course of prosecution, it is incumbent on the examiner to cite this prior art against the claimed invention.

13.07 Examiner's reports

June 2015

An examiner's report is an examiner's official means of communicating with an applicant. A report will contain at least one requisition as well as information provided to clarify the scope or content of each requisition. A report will also indicate the time limit within which the applicant must respond to each requisition in order to avoid abandonment. [For more information on abandonment and time limits see Chapter 20 of this manual.]

Under subsection 30(2) of the *Patent Rules*, where an examiner has reasonable grounds to believe that an application does not comply with the *Patent Act* and *Patent Rules*, the applicant must be informed of the application's defects and must be requisitioned to amend the application to comply or to provide arguments as to why the application does comply. Where an examiner has identified one or more defects, these will be detailed in the report and, for the purposes of paragraph 73(1)(*a*) of the *Patent Act*, they are considered to be a single requisition. The beginning of this requisition can generally be identified in a report by text such as "The examiner has identified the following defects in the application". The requisition ends with a paragraph such as "In view of the foregoing defects, the applicant is requisitioned, under subsection 30(2) of the *Patent Rules*, to amend the application in order to comply with the *Patent Act* and the *Patent Rules* or to provide arguments as to why the application does comply".

Reports may also include additional requisitions under sections 29, 89 and 104.1 of the *Patent Rules*. More information on these types of requisitions is given in sections 13.07.01,13.07.02 and 13.07.03.

Each separate requisition made in a report must be responded to within the time period indicated in the report or the application will be abandoned in accordance with paragraph 73(1)(*a*) of the *Patent Act*. For each requisition on the basis of which the application was deemed to be abandoned, a specific request for reinstatement must be made, a separate reinstatement fee must be paid, and any required actions must be taken.

An examiner's report will usually include additional content that does not form part of a requisition, but which provides useful information regarding the report. This content may indicate the date of the most recent amendments and, in the case of a first report, their origin (international stage or national stage), an indication of the number of claims on file, a statement regarding the search performed, and an identification of any prior art documents discovered and a discussion of their pertinence. The report may also include general comments on the prosecution and discussions relating to points raised by the applicant in their correspondence. Where there appears to be a disagreement between the applicant and the examiner as to the construction of the claims, the report may include the examiner's identification of the person skilled in the art and the common general knowledge. The report may also set out the examiner's understanding of the problem that the inventor set out to solve, the solution that the inventor has contemplated, and the essential elements that lead to that solution.

Where an examiner has deferred the search and examination of the claims this will be indicated in the report along with the reasons leading to the deferral. An examiner may, for example, choose to defer the search and examination of the claims in situations where a unity of invention defect is identified; where an application intended to be a divisional does not appear to be entitled to divisional status; or in situations where the examiner has determined that the claims are directed to non-statutory subject-matter.

13.07.01 Rule 29 requisitions

Section 29 of the *Patent Rules* provides that where an examiner "has reasonable grounds to believe that an application for a patent describing the same invention has been filed, in or for any country, on behalf of the applicant or of any other person claiming under an inventor named in the application being examined", the examiner may requisition from the applicant any of the following information and a copy of any related document:

(*a*) an identification of any prior art cited in respect of the applications;
(*b*) the application numbers, filing dates and, if granted, the patent numbers;
(*c*) particulars of conflict, opposition, re-examination or similar proceedings; and
(*d*) translations into English or French of all or part of a relevant document not in one of those languages.

An applicant must respond to such a requisition by providing the information requested or by specifically stating that the information is not available to them, and why this is. This latter statement, required under subsection 29(3) of the *Patent Rules*, must be provided even where the reason certain information is unavailable is that it does not exist. The position of the Office is that a translation is generally available to the applicant if the document to be translated is available to them.

When a request for examination is made, an Office letter is sent to the applicant to confirm the request for examination and to ask the applicant to consider voluntarily submitting the information referred to in section 29 of the *Patent Rules* as it becomes available to them. Voluntary submission of this information reduces the likelihood that an examiner will need to make a formal requisition to obtain it. Applicants should generally not submit information which is readily available to the examiner (see below). The object of the voluntary submission of prior art is to expedite prosecution by bringing the attention of the examiner to documents that might otherwise not be immediately identified at the outset of examination. Where a document is identified to the Office, the applicant should generally not submit a copy of the document unless they have reason to believe that copies of that document will not be readily available to the examiner.

Examiners should not requisition an identification of prior art cited in published search reports to which the examiner has ready access. Such search reports include the International Search Report, and any European Patent Office or United States Patent and Trademark Office search reports available through the respective web sites of those offices. Similarly, examiners should not requisition any information that is available to them through the web sites of those offices, including particulars of examination, opposition, or similar proceedings.

Recognising that translating documents may place a significant financial burden on the applicant, requisitions for translations should be limited to cases where no viable alternative exists.

Where a foreign language document appears relevant to examination, an examiner should attempt to locate a version of that document (or minimally of its abstract) in an Official language with which they can work. In this regard, examiners should make use of reliable online translation engines, such as that provided by the JPO, at least at the early stages of examination.

Where an examiner is working from a machine translation or from a family member of a citable document, this should be clearly stated in the report. An applicant wishing to rebut arguments made on the basis of such a document, however, may be required to provide a translation of the document to support their arguments.

Where a translation is requisitioned, the applicant must provide, in accordance with paragraph 29(1)(*d*) of the *Patent Rules*, a translation of the document, or a part of the document, into English or French. Where only a part of the document is necessary for examination, an examiner should indicate, wherever possible, in respect of which part or parts of the document the requisition for a translation is being made.

Under Article 42 of the Patent Cooperation Treaty (PCT), no national office having received an international preliminary examination report "may require that the applicant furnish copies, or information on the contents, of any papers connected with the examination relating to the same international application in any other elected Office". Article 42 of the PCT applies in respect of any national phase application that has been the subject of International Preliminary Examination under Chapter II of the PCT.

The Office considers that a requisition for the identification of prior art under paragraph 29(1)(*a*) of the *Patent Rules* or for application numbers, filing dates, and/or patent numbers under paragraph 29(1)(*b*) of the *Patent Rules* complies with the requirements of Article 42 of the PCT as the information being requisitioned is connected with the search of the prior art, and is not considered to be a request for copies of papers, or information on the contents of papers, "connected with examination".

Similarly, the Office does not consider conflict, opposition, re-examination and similar proceedings to be "connected with examination" in the sense intended by Article 42 of the PCT, and consequently requisitions under section 29 of the *Patent Rules* relating to such proceedings are also considered to be consistent with Article 42 of the PCT.

13.07.02 Rule 89 requisitions

Rule 89 requisitions pertain to the provision of certified copies of priority documents. This subject is covered in detail in chapter 15.

13.07.03 Rule 104.1 requisitions

Rule 104.1 requisitions pertain to the inclusion in the description of the date of deposit of biological material. This subject is covered in detail in chapter 17.

13.07.04 Withdrawal of an examiner's report

An examiner's report may be withdrawn where it is determined that the content of the requisition is inapplicable or unnecessary.

Such may be the case, for example, where an examiner's report and an applicant's amendment cross in the mail, and the report is by consequence no longer accurate.

Where an examiner's report is to be withdrawn, the examiner will notify Examination Support, who will cancel the report, remove the due date and inform the applicant in writing that the report is withdrawn. The examiner may also inform the applicant by telephone that the report has been withdrawn.

13.08 Amendment of the application

June 2015

Section 38.2 of the *Patent Act* provides that the specification and drawings of an application may be amended before a patent is issued as long as the amendment does not add matter not reasonably to be inferred from the originally filed specification or drawings, except in so far as it is admitted in the specification that the matter is prior art.

Once an application is allowed, the ability to amend the application is limited. Amendments to an application are discussed in chapter 19 of this manual.

13.09 Final Action

June 2015

In the course of examination, an examiner and applicant may come to an impasse regarding certain perceived defects of the application. Where this is the case, the examiner may, in accordance with subsection 30(4) of the *Patent Rules*, reject the application in a *Final Action* when there are reasonable grounds to believe that the application does not comply with the *Patent Act* and *Patent Rules*.

Practice related to *Final Actions* is covered in chapter 21 of this manual.

13.10 Refusal to grant a patent

June 2016

Section 40 of the *Patent Act* stipulates that whenever the Commissioner is satisfied that an applicant is not by law entitled to be granted a patent, the application shall be refused. Generally such a refusal does not occur unless the examiner has rejected the application in a *Final Action* in accordance with subsection 30(4) of the *Patent Rules,* and the Patent Appeal Board and the Commissioner of Patents have reviewed the rejected application.

More information on the refusal to grant a patent is found in chapter 21 of this manual.

13.11 Allowance and notice of allowance

June 2016

When an examiner believes that an application conforms to the requirements of the Patent Act and Patent Rules, the application will be approved for allowance. As per subsections 30(1) and 30(5) of the *Patent Rules,* the Commissioner will then notify the applicant that the application has been found allowable.[22] This notification is in the form of a notice of allowance requisitioning payment of the applicable final fee set out in item 6 of Schedule II of the *Patent Rules* within six months.

Subsection 30(6.2) of the *Patent Rules* provides that if, after a review of an application rejected by an examiner under 30(4) of the *Patent Rules* (i.e. after a *Final Action*) the Commissioner determines that the rejection is not justified, the Commissioner shall notify the applicant that the application has been found allowable.

Subsection 30(6.3) of the *Patent Rules* provides that if, after a review of an application rejected by an examiner under 30(4) of the *Patent Rules* (i.e. after a *Final Action*) the Commissioner determines that the application does not comply with the *Patent Act* or *Patent Rules* but that specific amendments are necessary, the Commissioner shall notify the applicant that the specific amendments have to be made within three months. If the applicant complies with the notice, the Commissioner shall notify the applicant that the application has been found allowable.

The application is "allowed" on the date at which the notice of allowance is sent. Once an application is allowed, prosecution before the examiner has technically ceased. In certain situations, an amendment after allowance may be possible; see chapter 19 of this manual for more information on this topic.

Failure to pay the final fee will result in abandonment in accordance with paragraph 73(1)(*f*) of the *Patent Act*. An application that has been reinstated after being abandoned for failure to pay the final fee may be amended, and is subject to further searching and examination.

Where an application is abandoned for failure to pay the final fee, paragraph 30(10)(*a*) of the *Patent Rules* provides that upon reinstatement, the original notice of allowance is deemed never to have been sent. In accordance with paragraph 30(10)(*b*) of the *Patent Rules*, a further notice of allowance will not requisition payment of the final fee unless the final fee submitted to effect reinstatement has been refunded.

Under paragraph 4(10)(*b*) of the *Patent Rules*, a final fee may be refunded if the request for refund is received before the technical preparations for issuance are begun..[23]

13.12 Withdrawal from allowance

June 2015

Subsection 30(7) of the *Patent Rules* provides that if, after a notice of allowance is sent but before a patent is issued, the Commissioner has reasonable grounds to believe that the application does not comply with the *Patent Act* or *Patent Rules*, the Commissioner shall notify the applicant of that fact, withdraw the notice of allowance, refund the final fee (if it has been paid), and return the application to the examiner for further examination.

An application may be withdrawn from allowance, for example, in view of applicable prior art identified in a protest or in a filing of prior art under section 34.1 of the *Patent Act*.

In such cases the notice of allowance is deemed never to have been sent, nor (if applicable) the final fee to have been paid, and the provisions of sections 32 and 33 of the *Patent Rules* do not apply.

13.13 Issuance of a patent

April 2017

Upon payment of the final fee referred to in section 13.11, the Office will process the application to grant, and will generally issue the patent on a Tuesday approximately six weeks after payment of the final fee. The patent will issue in the name(s) of the inventor(s), or to the legal representative(s) on the basis of appropriate documentation such as assignments received no later than the day on which the final fee is paid.

If a maintenance fee is due shortly after payment of the final fee, the Office postpones issuing the patent until the maintenance fee is paid. The reason for this is to avoid a situation where an application goes abandoned for failing to pay the maintenance fee, yet the patent is granted because the technical preparations for issue started before the application went abandoned.

Endnotes for chapter 13

[1] Applications are assigned to an examiner working in the field to which the claimed invention belongs, and are examined sequentially, according to the request for examination date.

[2] *Canada (Attorney General) v. Amazon.com Inc.*, 2011 FCA 328 [*Amazon* FCA] at paragraph 43

[3] Purposive construction is performed by the court to objectively determine what the person skilled in the art would, as of the date of publication of the patent application and on the basis of the particular words or phrases used in the claim, have understood the applicant to have intended to be the scope of protection sought for the disclosed invention (see *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66 at paragraph 50; and *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67 at paragraph 48).

Free World Trust and *Whirlpool* continue to guide the courts, with the benefit of expert testimony and cross-examination, to construe the claim in accordance with the principles of purposive construction outlined therein. (For an enumeration of the principles, see *Free World Trust* at paragraph 31).

However, *Whirlpool* was an impeachment proceeding that was not directed "to patent examiners in the course of examinations to determine whether applications for patents should be granted." (see *Genencor International Inc. v. Canada (Commissioner of Patents)*, 2008 FC 608 [*Genencor*] at paragraphs 62 and 70).

It should be recognized that the language of patent claims construed by judges is fixed, is the result of a negotiation with the Patent Office, was "accepted by the Commissioner of Patents as a correct statement of a monopoly that can properly be derived from the invention disclosed in the specification" (see *Whirlpool* at paragraph 49) and benefits from the presumption of validity accorded by subsection 43(2) of the *Patent Act*. In contrast, during examination of an application the language of the claim may change from that initially proposed by the applicant for a number of reasons (see *Genencor* at paragraphs 62 and 70 and *Amazon* FCA at paragraph 73).

[4] *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66 at paragraph 50; Whirlpool Corp. v. Camco Inc., 2000 SCC 67 at paragraph 48

[5] *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67 at paragraphs 49(f)(g), 52 and 53

[6] *Free World Trust v. Électro Santé Inc.*, (supra at 4) at paragraph 51

[7] *Amazon FCA* (supra at 2) at paragraph 73

[8] *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77 at paragraph 37; the Supreme Court in *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60 at paragraph 32 reiterates this point, and speaks of the importance of the patent bargain in advancing science and technology.

[9] *AstraZeneca Canada Inc. v. Apotex Inc.*, 2010 FC 714 at paragraph 33; *Wenzel Downhole Tools Ltd. v National-Oilwell Canada Ltd.*, 2011 FC 1323 at paragraph 61; *Jay-Lor International Inc. v. Penta Farm Systems Ltd.*, 2007 FC 358 at paragraph 55; *Sanofi-Aventis Canada Inc. v. Apotex*, 2009 FC 676 at paragraph 128; *Merck & Co. Inc. v. Apotex Inc.*, 2010 FC 1265 at paragraph 86

[10] *Amazon FCA* (supra at 2) at paragraph 43

[11] *Amazon* FCA (supra at 2) at paragraph 42. It is also stated that the examiner must be "alive to the possibility that a patent claim may be expressed in language that is deliberately or inadvertently deceptive", thus recognizing that, "for example, what appears on its face to be a claim for an "art" or a "process" may, on a proper construction, be a claim for a mathematical formula and therefore not patentable subject matter" *(see Amazon* FCA at paragraph 44).

[12] *Free World Trust* (supra at 4) at paragraph 58

[13] *Free World Trust* (supra at 4) at paragraph 55

[14] *Amazon FCA* (supra at 2) at paragraphs 59 to 63; following the reasoning of the court, the existence of a practical embodiment does not automatically imply that the elements of the embodiment are essential elements of the invention.

[15] *Free World Trust* (supra at 4) at paragraph 52

[16] *Halford v Seed Hawk Inc.*, 2006 FCA 275 at paragraph 14

[17] The Office does not consider the "self-inflicted wound" factor to be relevant during examination.

[18] Examiners should be mindful that, in this context, the identification of multiple problems and solutions within a single claim is not to be confused with lack of unity of invention within the meaning of section 36 of the *Patent Rules* (which emphasizes that the subject matter defined by the claims are to be linked by a single general inventive concept).

[19] *Re Application for Patent of Prince Corp.*, 1982, 2 C.P.R. (3d) 223 (CD 942); and *Shmuel Hershkovitz v. Tyco Safety Products Canada Ltd.*, 2009 FC 256 at paragraph 148

[20] The "claim date" of a claim in an application or patent is the filing date of the application in Canada, unless there is a priority claimed. In the latter case the claim date is the filing date of the earliest priority application which supports the subject matter of the claim.

[21] Searches performed by Canadian examiners as part of CIPO's obligations as an International Searching Authority are governed by the requirements of the PCT, and are not covered by this section of the manual.

[22] Subsection 30(1) applies where a final action was not issued, and 30(5) where the application is found allowable subsequent to a response to a final action.

[23] This refers to a final fee paid by the authorized correspondent on an application that has been allowed.

Chapter 14
Unity of Invention

14.01 Scope of this chapter

November 2013

The Canadian *Patent Act* and *Patent Rules* are based in part on the simple premise of *one patent for one invention.*[1] The concept of unity of invention refers to the requirement that an application claim *one invention only*. This requirement serves, in part, to ensure that the fees paid by applicants are fairly assessed on a per invention basis.

Requiring that a patent relate to *one invention only* also provides a measure of clarity to the patent system, by constraining the scope of individual patents. A patent specification directed to a single invention is clearer and more readily understood than one that attempts to describe and define several.

The present chapter deals with the subject of unity of invention from two perspectives. First, the assessment by an examiner of whether or not, for the purposes of examination, an application claims more than one invention, and with the procedures for dealing with an application that does and second, the framework and requirements for the filing of a divisional application to protect an invention other than the invention to which the claims of its parent application are limited.[2] The term "parent" is used to refer to an application that describes more than one invention, and which served as the basis for the filing of a further application (a "divisional" application) to protect an invention other than the one ultimately claimed in the parent.

Note that throughout the chapter the term "invention" is used to refer to subject-matter that an applicant alleges to be an invention (an "alleged invention"). Where, when assessing unity of invention, an examiner identifies a plurality of inventions in a claim set, this should not be taken as a suggestion that all of the several inventions thus identified have been assessed for patentability.

14.02 Unity of invention

November 2013

The basic framework that governs unity of invention is section 36 of the *Patent Act*, which provides that

> *(1) A patent shall be granted for one invention only but in an action or other proceeding a patent shall not be deemed to be invalid by reason only that it has been granted for more than one invention.*

Unity of invention has been referred to as "essentially a procedural matter",[3] as it does not of itself give rise to issues of validity. Section 36 of the *Patent Act* also sets out provisions whereby the claims are to be limited to *one invention only* and any additional inventions described (or described and claimed, as the case may be) may be protected by the filing of separate and distinct applications therefor. Thus

> *(2) Where an application (the "original application") describes more than one invention, the applicant may limit the claims to one invention only, and any other invention disclosed may be made the subject of a divisional application, if the divisional application is filed before the issue of a patent on the original application.*

and

> *(2.1) Where an application (the "original application") describes and claims more than one invention, the applicant shall, on the direction of the Commissioner, limit the claims to one invention only, and any other invention disclosed may be made the subject of a divisional application, if the divisional application is filed before the issue of a patent on the original application.*

As discussed in the following sections, it is important to approach the concept of unity of invention bearing in mind its legal context and purpose, and not to confuse it with the determination of whether or not one invention is "the same" as another such as is done, for example, when assessing novelty or double patenting and during re-issue proceedings.

14.03 Meaning of "one invention only"

November 2013

In interpreting section 36 of the *Patent Act*, the term "invention" in the expression "one invention only" is best understood as having a broad meaning. The broad interpretation of the meaning of the term "invention" in section 36 of the *Patent Act* is reflected in section 36 of the *Patent Rules*, which provides that

> *For the purposes of section 36 of the Act or of the Act as it read immediately before October 1, 1989, an application does not claim more than one invention if the subject-matters defined by the claims are so linked as to form a single general inventive concept.*

In interpreting the scope of section 36 of the *Patent Act*, the Courts have ascribed to the term "invention" a meaning different than that provided in section 2 of the *Patent Act*.[4] The Courts thus spoke of claims to matter in different categories of invention as being "aspects of a single invention". A similar, broad interpretation of the meaning of "invention" has been ascribed by the Courts in considering other provisions of the Act.[5] It is clear that the Courts have considered that the legislative intent of section 36 of the *Patent Act* is not fulfilled by interpreting the expression "one invention only" by giving the term "invention" its definition from section 2 of the *Patent Act*. That is, section 36 of the *Patent Act* should not be understood to say *where an application (the "original application") describes and claims more than one new and useful art, process, machine, manufacture or composition of matter [...], the applicant shall [...] limit the claims to one invention only [...].*

Thus, as directed by section 36 of the *Patent Rules*, an application will not be considered to claim more than one invention if the subject-matters defined by the claims are so linked as to form a single general inventive concept.

14.04 Canadian unity standard harmonious with PCT standard

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The 1996 revision of the *Patent Act* and *Patent Rules* had as one of its objects the harmonization of the Canadian patent framework with the *Patent Cooperation Treaty* standards.[6]

This can be readily appreciated by comparing the language of section 36 of the *Patent Rules* with that of section 13.1 of the *Regulations Under the PCT*, which states that

> *The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").*

The phrase "one invention only" in section 36 of the *Patent Act*, when understood in its full context and in view of section 36 of the *Patent Rules* (as discussed in 14.03), has a meaning equivalent to "one invention only or to a group of inventions so linked as to form a single general inventive concept" in Rule 13.1 of the *Regulations Under the PCT*.

The result is that the Canadian unity of invention requirement is not "different from or additional to" that provided for in the *Patent Cooperation Treaty*. Identifying a defect arising from non-compliance with the requirements of section 36 of the *Patent Act* does not contravene article 27(1) of the *PCT*.[7]

14.05 General inventive concept

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Assessing whether or not unity of invention exists in a given claim set amounts to determining, having regard to the specification as a whole, whether or not a "single general inventive concept" exists to link the claims.[8]

The inventive concept can be identified by considering the purpose of the invention. The claimed invention should provide a solution to a practical problem, and claims that define that solution or refinements to that solution (or of how it is to be put into operation or manufactured, as the case may be) may all relate to a single inventive concept. Generally, a set of claims will share a general inventive concept if a set of new and unobvious elements is common to each claim in the set, provided the elements in question are those required for the proper operation of the invention in its broadest aspects.

The inventive concept relates to how a result is obtained (i.e. to the inventive aspects of a practical solution to a problem), and not simply to the idea of obtaining the result *per se*. The correct standard to consider is that of unity of invention (i.e. unity among the solutions to a problem), rather than "unity of result". Mutually unobvious means (practical forms) for achieving a given result will generally not share a single general inventive concept.

The PCT expresses the concept similarly, in Rule 13.2 of the *Regulations Under the PCT*, which states that

> *Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.*

The expression "special technical features" used in the PCT Regulations refers to novel and unobvious elements of the claims that are responsible for the proper operation of the invention.

14.06 *A priori* and *a posteriori* evaluation

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Claims that have in common a set of new and unobvious elements [as described in 14.05] satisfy the requirement for unity of invention.

The two aspects of the unity of invention requirement can be considered separately as: 1) the need for a common set of elements among the claims, and 2) the requirement that the common set of elements be new and unobvious (*i.e.* inventive) over the prior art.

The former can be assessed without regard to the state of the art, and is referred to as an *a priori* evaluation of unity of invention, whereas the latter requires the state of the art to be considered and is referred to as an *a posteriori* evaluation. A lack of unity of invention is a defect in an application regardless of whether it is identified *a priori* or *a posteriori*.

A typical approach for assessing whether the claims have unity of invention is to identify the claim with the fewest elements, and then check to see if those same elements appear in all the other independent claims. The claims may appear to lack unity of invention *a priori* where no claim defines solely those elements that are common to all the claims, however the absence of such a claim is not determinative since there is no requirement that there be one claim broader than all others, nor that there be only one independent claim in each category of *invention* [see 14.08.02 for additional guidance on this point].

In assessing whether a common set of elements is present, the language of section 13.2 of the *Regulations Under the PCT* should be borne in mind - that the claims must include "the same or corresponding special technical features". The concept of "corresponding" means that two claims can have unity of invention even if they do not share a set of precisely identical elements, but rather share equivalent elements whose roles in the context of the invention correspond.[9]

Any prior art relevant for a determination of anticipation or obviousness under section 28.2 or 28.3 of the *Patent Act* may be considered in assessing whether unity of invention exists [see chapter 15 of this manual].

Example 1:

[This example sets forth an *a priori* analysis.]

An application discloses a paint containing a rust-inhibiting substance X, a process for applying said paint with substance X and an electrode arrangement A for applying paint. The electrode arrangement is useful for applying paint in general, and is not required in order to apply the paint comprising substance X (the benefits of having substance X in the paint are unrelated to how the paint is applied).[10]

Claims:

1. A paint comprising a rust-inhibiting substance X.

2. An apparatus for electrostatically charging atomized particles, comprising an arrangement of electrodes A.

3. An apparatus for electrostatically charging atomized particles, comprising an arrangement of electrodes A, wherein said apparatus is for applying the paint of claim 1.

4. A process for painting an article, said process comprising the steps of
i) atomizing the paint of claim 1 using compressed air;
ii) electrostatically charging the atomized paint using an electrode arrangement A; and
iii) directing the paint to the article.

Analysis: An *a priori* assessment of the claims reveals two alleged inventions: the paint comprising substance X and the apparatus including electrode arrangement A. The special technical feature of claim 1 is substance X. The special technical feature of claim 2 is electrode arrangement A. Substance X and electrode arrangement A do not cooperate in any way. Claim 4 includes the technical features of both claims 1 and 2. Claim 3 makes reference to the technical features of both claims 1 and 2, but it must be determined whether the reference to the paint of claim 1 implies a practical limitation to the structure of the apparatus. If the apparatus of claim 2 is suitable for painting the paint of claim 1 (as it seems to be, in view of claim 4), then claim 3 defines the same apparatus as claim 2 and would lack unity of invention with claim 1 despite the reference to that claim.

There is an *a priori* lack of unity between claims 1 and 2, since the two claims do not share a technical feature in common. Unity of invention does exist between claims 1 and 4 (on the basis of the paint comprising substance X) and between claims 2, 3 and 4 (on the basis of the electrode arrangement A).

Note that while claim 4 can be included in an application with either claim 1 or claim 2, if it was maintained in the parent and filed in a divisional application the result would be double-patenting. Therefore, the subject-matter of claim 4 may be included in the claims of the parent or of the divisional, but not both.

Example 2:

[This example sets forth an *a posteriori* analysis.]

The application describes a computer monitor comprising elements A and B, and further discloses that additional elements C and D lead, respectively, to particular advantages.

A search of the prior art reveals document D1, which discloses a computer monitor comprising elements A and B.

Claims:

1. A computer monitor comprising elements A and B.

2. A computer monitor according to claim 1, further comprising element C.

3. A computer monitor according to claim 1, further comprising element D.

Analysis: The claims meet the requirement for unity of invention on an *a priori* assessment, since elements A and B are common to each claim. In view of D1, however, these elements do not provide a general inventive concept that links the claims. To the extent that elements C and D have each been disclosed in the application as leading to particular, mutually unobvious advantages, claims 2 and 3 are directed to distinct inventions that lack unity of invention *a posteriori*.

If, on the other hand, it is clear to the examiner from the description and/or the prior art that features C and D do not provide inventive solutions to any practical problem facing the art (and are therefore not the result of further invention over the matter of claim 1), such that D1 renders claims 2 and 3 either anticipated or obvious, then only the consequent defects under sections 28.2 and/or 28.3 of the *Patent Act* should be identified. No defect under section 36 of the *Patent Act* should then be identified, although the examiner may note the potential lack of unity that might exist once the prior art defects are addressed [see 14.07.03].

14.07 Examining for unity of invention

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The Office takes the position that the intent of subsection 36(1) of the *Patent Act* is that where an application describes and claims more than one invention, the claims require amendment so as to define *one invention only*. A lack of unity of invention among the claims is identified as non-compliance with subsection 36(1) of the *Patent Act* and the applicant is notified of the defect and requisitioned to correct it or to submit arguments as to why the claims do comply with section 36 of the *Patent Act*. This notification is made in an examiner's report issued under subsection 30(2) of the *Patent Rules*.

Given that, where a lack of unity of invention has been identified, the examiner cannot be certain which invention the applicant will elect to maintain in the claims, a report identifying non-compliance with section 36 of the *Patent Act* need only identify this defect. This is an exception to the usual requirement that a requisition under subsection 30(2) of the *Patent Rules* be based on a comprehensive examination [see section 13.05 of this manual]. In this sense, addressing a question of unity of invention can be viewed as a procedural matter to be resolved separately from the substantive examination of the application.

Where the applicant responds to a requisition identifying a lack of unity of invention by amending the claims in such a manner as to overcome the defect, this determines for that application the *one invention only* referred to in subsection 36(2) of the *Patent Act* [see 14.03]. Thereafter, *any other invention disclosed may be made the subject of a divisional application*. The Office takes the position that, in accordance with subsection

36(2) of the *Patent Act*, the claims of the original application [see 14.11] under examination may no longer be directed to the matter of *any other invention disclosed*. In responding to an examiner's report identifying a lack of unity of invention, the applicant effectively has the right to elect, one time only, the identity of the *one invention only* that will be the subject of examination in a given application.

Claims resulting from post-election amendments will generally be permissible in the application if they would have had unity of invention with the claims to the *one invention only* elected by the applicant.

To avoid prolonged debate over unity of invention, where an examiner considers that the claims lack unity of invention and the applicant declines to limit their claims to a single invention, the examiner may refer the application to the Commissioner of Patents for a determination of the issue. Typically, such a referral will not occur until the examiner has advised the applicant of the defect in at least two reports.

This referral will not take the form of a Final Action, since:

> (a) should the applicant limit the claims to *one invention only* in response to a Final Action, subsection 30(5) of the *Patent Rules* would require the examiner to withdraw the rejection; this should generally result in allowance of the application, but in the case of a lack of unity of invention the claims would generally not have been fully examined; and
>
> (b) should the Commissioner conclude after a review in accordance with subsection 30(6) of the *Patent Rules* that the application does not comply with subsection 36(1) of the *Patent Act*, no further amendment of the application would be possible in view of section 31 of the *Patent Rules*.

Where a review of the application [see 14.07.06] leads to the conclusion that the application complies with section 36 of the *Patent Act*, the examiner will resume prosecution and consider all the claims on file.

Where the Commissioner reviews the application and has reason to believe that it does not comply with section 36 of the *Patent Act*, a letter will be sent to the applicant directing that the claims be limited to *one invention only*. This direction will be made under authority of subsection 36(2.1) of the *Patent Act*, and is not a requisition under section 30 of the *Patent Rules*.

Where the applicant's amendments in response to the letter make the application compliant with section 36 of the *Patent Act*, examination of the application will continue. If the applicant's amendments in response to the letter fail to satisfy the Commissioner that the application complies with section 36 of the *Patent Act*, the application may be refused under section 40 of the *Patent Act*.

14.07.01 Content of the report

Whenever a report is written that identifies lack of unity of invention as a defect, an indication must be included in the report of the extent of the search and examination performed on the application as a whole.

As noted in 14.07, a report identifying a lack of unity may be limited in scope to address only that defect. This will usually be the case where a lack of unity is identified at the outset of prosecution. Where a lack of unity is identified later in prosecution, the facts of the case may be such that it is more efficient to identify this defect in parallel with a comprehensive examination of some or all of the claims, rather than interrupting the substantive examination in order to deal with the unity of invention defect alone.

Even where a lack of unity of invention is identified as a defect at the outset of prosecution, if the examiner believes (for example, in view of corresponding patents issued in other jurisdictions) they know which group of claims an applicant will elect for prosecution, they may include in their report an identification of all the defects associated with these claims. The choice of the examiner does not replace the applicant's right to make their one-time election [see 14.07]. If the applicant elects a different group of claims for prosecution from the one the examiner chose to examine, prosecution proceeds on the basis of the claims elected by the applicant.

Where there are defects in the application that affect the determination of unity of invention, an examiner may refer to these defects in addition to or instead of the lack of unity defect and should set out how the other defects impact the assessment of unity of invention or vice versa. Defects such as lack of clarity in the claims, or prior art that leads to a conclusion of *a posteriori* lack of unity of invention are illustrative of the types of additional defects whose resolution may impact the determination. To avoid confusion as to the necessary response by the applicant, it may be preferable to identify such defects informally (e.g. in the preamble of the report, or by otherwise explicitly indicating that the defect is not being formally identified), solely to explain the impact they had on assessing unity of invention.

14.07.02 Explaining a lack of unity defect

A report identifying a lack of unity of invention should explain the basis for the conclusion in a manner that will enable the applicant to decide whether and how to limit or divide their claims for further examination. This explanation should identify what the examiner considers the various distinct inventions to be, and should provide sufficient detail so that the applicant can understand why the different inventions do not share a single general inventive concept. Where the defect is identified *a posteriori*, the prior art supporting this conclusion should be cited in the report and an explanation of the significance of each document should be provided.

Wherever possible, the individual inventions identified should be related to the claims in which they are defined, so that the applicant can group their claims into sets which would be viewed by the Office as sharing a single general inventive concept. This will generally be done in all cases unless attempting to relate each invention to a specific claim or claims would only introduce a lack of clarity into the explanation of the defect. Other than in exceptional cases, the examiner will set out groups of claims that are considered to be directed to *one invention only*. When creating such groups, the examiner should clearly indicate to which group each independent claim belongs. Unless an explicit indication has been made by the examiner with respect to a given dependent claim, the applicant may presume that a dependent claim belongs to the group in which the claim it refers to is found.

Where a lack of unity exists among the alternatives defined in a single claim, the examiner will, to the extent practical, separate the various inventions into groups. In such a case, unless otherwise indicated by the examiner, a dependent claim belongs to the group in which the alternative it refers to is found.

As a general rule, if the applicant limits the claims in the application to one group of claims identified by the examiner, the application will be considered to have been made compliant with section 36 of the *Patent Act*. Certain exceptions to this general rule exist, however, such as where a further lack of unity of invention subsequently becomes apparent in view of prior art discovered after the applicant has elected a group of claims for prosecution.

Note that in identifying the various inventions in a claim set, the term "invention" is used as a matter of convenience only, and in no way implies that the subject-matter of any given claim is patentable.

14.07.03 When a lack of unity defect can be identified

In general, a lack of unity of invention should be identified in the first report written in respect of the claims that lack unity of invention.

In some cases, an examiner may identify defects in an application that bear on the question of whether the claims have unity of invention (e.g. obviousness, ambiguity, lack of utility or of support). Where the applicant's response in respect of the other defects is germane to its evaluation, it is permissible for the lack of unity of invention defect to be formally identified in a later report. Whenever possible, the applicant should be advised that the other defects bear on the question of unity of invention.

Since unity of invention is assessed in view of the claims of the application, a lack of unity of invention may be introduced when amendments are made to the claims. Where a lack of unity of invention is introduced by the applicant with an amendment, an examiner may identify the resultant defect regardless of the length of prior examination of the application.

Where prior art raises the possibility of *a posteriori* lack of unity, but some of the claims in the application are considered by the examiner to be anticipated or obvious in view of the cited prior art, it may be preferable to not identify the lack of unity of invention as a formal defect until the prior art defect has been addressed by the applicant. The applicant's response to the prior art defect may advance the examiner's understanding regarding unity of invention. The examiner may draw the applicant's attention, informally [see 14.07.01] and depending on the circumstances, to the potential unity defect.

If the applicant responds to a prior art objection by amending the claims, and the claims as amended appear to avoid the cited prior art but to lack unity of invention, an examiner may identify the lack of unity defect.

14.07.04 Responding to a requisition

As with any requisition sent under subsection 30(2) of the *Patent Rules*, an applicant may respond to the identification of a lack of unity of invention by amending the application (in order to comply with subsection 36(1) of the *Patent Act*) or by submitting arguments as to why the application already does comply.

Where the applicant amends the claims by limiting them to claims falling within a single group identified by the examiner, the lack of unity defect identified in the issued report will be considered to have been overcome in respect of those claims [see 14.07.02].

Should the applicant agree that there is a lack of unity of invention among the claims, but disagree as to the grouping of claims set out by the examiner, they may respond to the requisition by identifying groups of claims different from those identified by the examiner and electing one of those groups of claims.

Where the applicant's response to the requisition does not serve to make the claims compliant with the requirement for unity of invention, a further report identifying the lack of unity defect may be sent.

14.07.05 Election of an invention

The applicant will be considered to have elected an invention whenever, subsequent to a report in which a lack of unity of invention was identified as a defect, the applicant limits the claims to fewer inventions than were defined in the claim set with respect to which the lack of unity of invention was identified. It is not necessary for the applicant to explicitly state that they have "elected the invention of Group A" when making an election (although this may certainly be done by the applicant, in the interest of greater clarity).

Where the applicant's initial election limits the claims to a single invention, this defines the *one invention only* referred to in subsection 36(2) of the *Patent Act* [see 14.07].

Where the applicant initially elects more than one group of claims identified by the examiner, or claims belonging to more than one group of claims identified by the examiner, or even submits new claims entirely, any further election that may be necessary (i.e. should the initially elected claims still lack unity of invention) must be made from among the inventions defined in the initially elected claim set.

14.07.06 Referral to the Commissioner of Patents

As noted in 14.07, where an examiner considers that the claims lack unity of invention and has notified the applicant of this conclusion, but the applicant declines to limit their claims to a single invention, the application may be forwarded to the Commissioner of Patents for a determination of the issue.

Resolving questions of unity of invention should be conducted efficiently, since the substantive examination of the application is delayed by this procedure. Consequently, if an applicant has been notified of a lack of unity of invention defect in at least two reports they should expect that a referral to the Commissioner could be made without further notification.

To ensure consistency and fairness, where an examiner considers that an application should be referred to the Commissioner, they must first submit the application for review by a Unity Review Board (URB). This board will review the application in order to ensure the lack of unity defect was correctly identified and clearly articulated to the applicant, so that the applicant was in a position to successfully respond to the examiner's requisition.

Where the URB considers that unity of invention exists, the examiner will proceed with the substantive examination of all claims on file.

Where the URB considers that a lack of unity of invention exists, but that further clarification of the matter is necessary (e.g., further reasons for concluding a defect exists, or additional information regarding the identity of acceptable claim groups), the examiner will issue a further report taking into account the observations of the URB.

Where the URB considers that a lack of unity of invention exists, and has been clearly communicated to the applicant in an examiner's report such that the applicant could have responded successfully to the examiner's requisition, the application will be forwarded to the Commissioner of Patents for consideration.

Where the Commissioner considers it appropriate, the applicant will be directed to limit the claims under authority of subsection 36(2.1) of the *Patent Act*. A Notice of Direction will then be sent to the applicant by the Commissioner.

Where the applicant's response to the Notice of Direction does not satisfy the examiner that the application complies with section 36 of the *Patent Act*, the application will be forwarded to the Patent Appeal Board for a final review. At this stage, the process resembles the review of a Final Action [see chapter 21 of this manual], given that the Patent Appeal Board may recommend that the Commissioner refuse the application under section 40 of the *Patent Act*. In accordance with subsection 30(6) of the *Patent Rules*, an application will not be refused without the applicant being given an opportunity to be heard.

14.08 Specific guidance

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The following sections provide more specific guidance on assessing unity of invention.

14.08.01 Claims in different categories of *invention*

In general, it can be presumed when assessing unity of invention *a priori* that claims in the following categories of invention will satisfy the requirements of section 36 of the *Patent Rules* when present in a single application:

(*a*) a product and a process for making that product;
(*b*) a product and a use (or method of using) that product;
(*c*) a product, a process for making that product, and a use of that product;
(*d*) an apparatus and a process carried out on that apparatus.

Where the "process for making a product" of (*a*) or (*c*) is a "process carried out on an apparatus" within the meaning of (*d*), claims to the apparatus can be included in a single application with claims to the product, process for making the product and use of the product so long as the product is inventive by reason of properties that arise by virtue of its being prepared using the apparatus.

Note that it is not required that the scope of the claims to subject-matter in different categories of invention be of similar breadth in order to satisfy the requirement of unity of invention. Where the scopes are equivalent, unity will generally exist *a priori*. Where the scopes are different, unity may still exist.
For example, a broad process for using products could have unity of invention with a narrow product claim defining only a limited number of the products used in that process

(see Example 2, below).

Example 1:

An application discloses a fuel burner wherein the use of inlets arranged tangentially to the mixing chamber results in better mixing and more efficient combustion.[11]

Claims:

1. A fuel burner comprising tangential fuel inlets into a mixing chamber.

2 A process for making a fuel burner, comprising the step of forming tangential fuel inlets into a mixing chamber.

3. A process for making a fuel burner comprising casting step A.

4. An apparatus for carrying out a process for making a fuel burner, comprising feature X which causes the formation of tangential fuel inlets.

5. An apparatus for carrying out a process for making a fuel burner comprising a protective housing B.

6. A process of manufacturing carbon black, comprising the step of tangentially introducing fuel into a mixing chamber of a fuel burner.

Analysis: Unity of invention exists, *a priori*, among claims 1, 2, 4, and 6. The special technical feature apparently common to these claims is the tangential fuel inlets. Claims 3 and 5 lack this feature, or a corresponding feature [see 14.06], and therefore lack unity of invention both with respect to each other and to the remaining claims. A lack of unity of invention might be identified *a posteriori* once a search of the prior art had been performed.

Example 2:

An application discloses the discovery that certain compounds, some novel and others known, are useful as plant growth regulants. The compounds are disclosed as a genus (a family of molecules) of common formula A, which comprises specific molecules a_1, a_2, a_3, ..., a_n. Compounds belonging to the sub-genus A' are disclosed as being novel, and a_1 is taught as a particularly preferred embodiment. No prior art is cited against the novelty of the compositions of claim 1.

Claims:

1. A plant growth regulant composition comprising a compound of formula A and a carrier. 2. A process for regulating plant growth comprising the step of applying

a plant growth regulant composition of claim 1 to a plant.

3. A compound of formula A'.

4. Compound a_1.

Analysis: The claims all define compounds that share a common structure that is responsible for their plant-growth regulant properties. The discovery that this structure results in plant-growth regulant properties (i.e. the allegedly new use of compounds A) appears to be the single general inventive concept linking the claims. There is *a priori* unity of invention among claims 1 to 4.

14.08.02 Unity without a claim to the inventive linking feature

Since unity of invention is initially assessed *a priori* in view of the claims and before the prior art is considered, a lack of unity of invention may be identified in a report where the subject-matter of the claims does not appear to share a single general inventive concept.

As noted in 14.05, a single general inventive concept is identified by finding common elements among the various claims. This is generally done by identifying the claim with the fewest elements, and then checking to see if those same elements appear in all the other independent claims. The claims may appear to lack unity of invention *a priori* where no claim defines solely those elements that are common to all the claims.

An applicant is not required to claim the entire scope of their invention, however, so a claim defining only the common elements is not required in order to provide a linking inventive concept. In performing an *a priori* assessment of unity of invention, an examiner must consider the teachings of the description and the common general knowledge in the art before concluding that the claims clearly lack a single general inventive concept. If it is clear that the description discloses a particular set of elements that are common to all the claims as being the general inventive concept, unity of invention *a priori* should be acknowledged.

Where an examiner identifies a lack of unity of invention *a priori*, an applicant may respond to a report identifying this defect by identifying those features which they consider to be the inventive elements common to all their claims. The examiner may subsequently verify this assertion by performing a search on the basis of those elements.

Example 1:

The application as filed discloses a class of compounds of formula X wherein all members of X are aliphatic organothiophosphates, methods for preparing compounds of formula X and uses of compounds of formula X as insecticides. The description does not suggest that the class of compounds forms part of the invention.

Claims:

1. A method of preparing a compound of formula X by combining a compound of formula A with a compound of formula B.

2. The use of a compound of formula X as an insecticide.

Analysis: An *a priori* assessment of unity of invention presumes the features defined in the claims are those necessary to render the claims novel and inventive. Independent claims 1 and 2 have compounds of formula X in common, but since such compounds have not been claimed it will be presumed (in view of the description) that they are not an invention in and of themselves. The claims therefore appear to lack unity of invention on an *a priori* basis. Note that no presumption exists that claims to a "method of preparing X" and to a "use of X" share unity of invention [see 14.08.01 for the combinations of claims for which a presumption of unity of invention exists].

If the applicant considers that the class of compounds of formula X are, in fact, novel and inventive, they could respond to a report identifying the apparent lack of unity of invention by asserting that fact. A search of the prior art on the compounds of formula X would validate this assertion. If such a search failed to disclose any relevant prior art, no further searching in respect of the claims would be necessary. If the search identified relevant prior art, the claims would lack unity of invention *a posteriori*.

Example 2:

The application as filed discloses that a class of known compounds of formula X, wherein all members of X are 3,4-substituted indoles, are 5HT receptor antagonists and are useful as migraine therapeutics and anti-depressants. The usefulness of 5HT receptor antagonists in treating both migraine and depression is known in the art, but the 5HT-antagonist activity of compounds of formula X had not previously been identified.

Claims:

1. The use of a compound of formula X as a migraine therapeutic.

2. The use of a compound of formula X as an anti-depressant.

Analysis: The general inventive concept resident in both claims is the discovery that the compounds of formula X are 5HT receptor antagonists. Although this feature is not explicitly defined in each claim, it is understood in view of the description to be the basis of the invention. When read in light of the description, the claims have unity of invention *a priori*.

14.08.03 Unity of invention and utility

An invention is something that is, *inter alia*, new, inventive and useful. The utility of claimed subject-matter can be indicative of whether one is dealing with a single invention or multiple inventions.

An applicant must establish the utility of their invention by either demonstration or sound prediction [see section 12.08.03 of this manual]. In cases where utility is being established by sound prediction, the nature of the prediction can inform the unity of invention inquiry. Where the claims include many embodiments, and the utility of all of these could be soundly predicted using a single line of reasoning founded on a single set of facts, it is likely that unity of invention exists among the claims. In contrast, if different parts of the claimed matter would require significantly different sound predictions to support their utility, it is likely that the claims include multiple inventions and that there is a lack of unity of invention.[12]

Where different embodiments within a given category of invention are claimed (e.g. species within an inventive genus), and the embodiments all share a generic utility, they may be viewed as aspects of a single invention. Where one embodiment has a significantly different utility than the others, it may also be viewed as a different invention.

Consider a drug of generic formula X for treating asthma and a species A within the genus, where A has significantly different utility from a typical drug X. If the substantially different utility exists in addition to the generic utility, the embodiment can be viewed both as an aspect of a single, larger invention and as a separate invention. Such a circumstance arises, for example, in the case of inventions with different levels of preferred embodiments and unity of invention would typically exist in such a case. Consider that species A treats asthma, but without a side-effect common to drug X in general. Species A is an inventive selection from drug X, and could either be claimed in a separate application or in the same application as the genus X.

If the substantially different utility exists in place of the generic utility, however, the one embodiment does not have the same utility as the other embodiments and is, by consequence, a different invention. Unity of invention would typically not exist in such a case. Here, species A turns out to be a very good decongestant but is not useful in treating asthma. It does not share unity of invention with the genus X.[13]

14.08.04 Markush groups and lists of alternatives

A Markush group must define a list of alternatives that, for the purposes of the claimed invention, can be viewed as technical equivalents that perform the same function in substantially the same way. The person skilled in the art should expect that one member of a Markush group is directly substitutable for another in operable embodiments of the invention. A Markush group is identified by the form "an [alternative] selected from the group consisting of [a_1, a_2, a_3, a_{n-1}], and [a_n]".

Markush groups are most common in the chemical arts; a group of chemical compounds may be appropriately defined in a Markush group if each alternative has a common property or activity and either

(*a*) shares a common structure with all other alternatives, wherein the shared structure is relevant to the activity of the alternatives in the invention; or

(*b*) belongs to a class of compounds recognised in the art to which the invention pertains and all members of the group would be expected to behave the same way in the context of the invention.

Where the alternatives defined in a Markush group do not satisfy the requirements of (*b*), and where unity of invention cannot be established by elements in the claim other than the Markush group, either the shared structure referred to in (*a*) or its utility in the context of the invention would need to be novel and inventive over the prior art in order to provide unity of invention to the claimed alternatives.

Where a list of alternatives satisfies the requirements set out above, unity of invention will generally be acknowledged whether the alternatives are claimed in the form of a Markush group or not.[14]

14.08.05 Intermediates and final products

An intermediate that is physically or chemically transformed to produce a final product may be considered to have unity of invention with the final product, despite that the inventive step and utility that support the patentability of the intermediate and final product may be quite distinct from each other.

The intermediate must, necessarily, be useful for producing the final product. It may also have the same utility as the final product, although this is not required.

To have unity of invention with the final product, the intermediate should share with the final product the principal structural elements of the final product or should serve to introduce to the final product a structural element that is essential to its utility. Different intermediates that introduce different structural parts to the final product, however, will generally not be considered to share unity of invention amongst each other.[15]

Furthermore, the intermediate must be a direct precursor to the final product, in the sense of being removed from the final product by only one or a few steps, and must not be a precursor to a subsequent intermediate that is known in the art and that must be produced on the way to the final product.[16]

The concept of "intermediates and final products" is common in chemical synthesis, but could apply in other arts as well.

Chemical examples of intermediates and final products that could be considered to have unity of invention include:

(i) a biologically inactive compound (the intermediate) that is deprotected to produce an active drug (the final product). The deprotection renders the final product active, but the overall structure of the intermediate and the final product are otherwise almost equivalent;

(ii) an intermediate in a multi-step synthesis that contains a structure which, upon ring-closing, produces a critical functionality in a final product, where the final product is prepared by reacting the intermediate with a polycyclic aromatic compound and subsequently ring-closing the structure introduced by the intermediate. The intermediate and the final product have very different structures, since the intermediate does not include the polycyclic scaffold of the final product. Nevertheless, the critical element of the final product results directly from the intermediate, and there are no known intermediates produced in the synthetic steps leading from the claimed intermediate to the final product.

Example 1:

An application discloses an industrially useful triazole compound defined by formula I, and a method for its preparation by ring-closure of a compound of formula II. The critical structure in the triazole product is the combination of the triazole ring (sub-structure A) with proximal substituted aromatic rings (structures B and D). The necessary stereochemistry of the groups A, B and D is provided by a central ring structure C. The description teaches that the ring structure C can be formed by a ring-closing reaction of functional groups E and F, which are present in the immediate precursor to the final product. The only disclosed utility of the intermediate is in the production of the final product.

Claims:

1. A compound of formula I comprising sub-structures A-B-C-D.

2. A compound of formula II comprising sub-structures A-B-E-F-D.

Analysis: Although the core structures of compound I (final product) and compound II (intermediate) differ considerably, compound II is an open-ring precursor to compound I. Both compounds share principal structural elements, namely the triazole A and the substituted aromatic rings B and D. The intermediate structure E-F is, from a chemical perspective, a known precursor for rings of type C. The two structures are, overall, technically closely interrelated and unity of invention exists.[17]

Example 2:

An application discloses two structurally related molecules A and B. Molecule A is a compound with analgesic properties. Molecule B results from selective methylation and acylation of two hydroxy groups on A. Compound B is not an effective analgesic, but has significant bioactivity as a sedative.

Claims:

1. A compound of structure A.
2. A compound of structure B.
3. A method for converting compound A into compound B through sequential selective methylation and acylation, comprising the steps [...].
4. A use of A as an analgesic.
5. A use of B as a sedative.

Analysis: Compound A is an intermediate that is structurally similar to compound B. Claims 1 and 2 share unity of invention, and share unity of invention with claim 3.

Claim 5 defines the use of compound B, and shares unity of invention with claims 2 and 3 (a product, process to produce the product and use of the product - see 14.08.01). Although claim 5 does not clearly share unity of invention with claim 1, claims 1, 2, 3 and 5 would typically be considered to have unity of invention in a single application (intermediate to produce B, compound B, process to produce B, and use of B).

Claim 4 lacks unity of invention with claims 2, 3 and 5 as it defines a use of intermediate A other than its use in preparing the final product or an equivalent use to the product's. Claim 4 (use of A) does share unity of invention with claim 1 (intermediate A). If desired, claim 3 could be included in an application with claims 1 and 4 (considering claim 3 to be a use of A), although in practice it would usually be preferable to include claim 3 in the same application as claims 2 and 5 (considering claim 3 to be a process to produce B).[18] Claim 4 could be claimed in a divisional application.

14.08.06 Multi-step methods of preparation

Some preparative methods will include more than one step that could be patentable independently of the multi-step preparative method as a whole. This applies particularly to multi-step synthetic methods, although in principle the concepts could apply to any multi-step preparative method (e.g. a method of manufacturing).

For the purposes of unity of invention, an application can include a claim to a single inventive transformative step in a method and to any larger method involving that step up to the entire multi-step method. The utility of the transformative step arises from it transforming a precursor (which will be a starting material or intermediate in the overall method) into a product (which may be a further intermediate in the method or its final product). The transformative step will also typically share unity of invention with its product, and may share unity of invention with certain of the product's precursors (see 14.08.05).

Other individual steps in the method (or combinations of steps that do not include the inventive transformative step), however, will not have unity of invention with the inventive transformative step. The other step or combinations of steps do not share the general inventive concept of transforming the inventive transformative step's precursor into its product. Products other than those meeting the "intermediate and final product" requirements set out in 14.08.05 will likewise be considered not to share unity of invention with the inventive transformative step and its product.

Consider a multi-step synthesis involving the following steps:

step A transforming 1 into 2;
step B transforming 2 into 3;
step C transforming 3 into 4;
step D transforming 4 into 5; and
step E transforming 5 into 6.

The applicant considers steps A and D to be inventive, as well as the 5-step method as a whole. Starting material 1 and intermediates 3 and 4 are known, while intermediates 2 and 5 and final product 6 are novel.

The application includes claims to step D, to step E, and to intermediate 5 and the closely structurally-related final product 6. Unity of invention can be acknowledged among these claims as involving inventive product 5, a method for producing product 5 (step D), a method of using product 5 (step E) and by virtue of the "intermediate / final product" relationship between products 5 and 6 [see 14.08.05]. Unity of invention could not be acknowledged between intermediate 5 and intermediate 2 because of the intervening known intermediates 3 and 4 [see 14.08.05], nor could individual steps A, B or C be claimed either alone or in any combination other than one ending with step D (i.e. so that the combination could be viewed as a method for producing 5).

It is worth noting that other groups of claims could be identified which would meet the requirement for unity of invention. For example, a claim to the 5-step method as a whole would have unity with a claim to product 6, to intermediate 5 and to any combination of steps that includes step E on the basis of the general inventive concept being "the preparation of 6 from 5".

14.08.07 Unity and provisos

A proviso is a clause added to a claim in order to remove something that would otherwise be encompassed by the language of the claim.

A proviso may be used, for example, to provide or restore novelty in cases where some part of the claimed subject-matter would otherwise be anticipated.

Whether a proviso causes a lack of unity of invention must be assessed on the facts of a given case. A proviso can be thought of as making the subject-matter of the claim "discontinuous", and in that sense can remove the generality of what would otherwise be a "general inventive concept".

In assessing whether a proviso will have the effect of removing unity of invention from the claimed subject-matter, the reason for including the proviso must be considered. Where a proviso is used to avoid prior art, for example, the critical question is whether the prior art has simply disclosed an embodiment falling within a claim or has taught the same inventive concept as the application. In the latter case, unity of invention is most likely absent in view of the proviso whereas in the former this may not be the case.

Example:

An application discloses a genus of compounds (compounds comprising the structure of formula I) useful as antibiotics. The inventors have discovered and disclosed a structure-function relationship based on a certain functional group in the genus. The same applicants had, several years earlier, obtained a patent on a species (species A) falling within the genus. At the time the previous patent was obtained, the applicants knew the species was a useful antibiotic but did not know what structure led to the activity.

Claims:

1. A compound comprising the structure defined by formula I, provided that said compound is not "species A".
2. A compound according to claim 1, wherein said compound is species B.
3. A compound according to claim 1, wherein said compound is species C.
4. A compound according to claim 1, wherein said compound is species D.

Analysis: The general inventive concept linking the compounds of formula I is the presence of the functional group responsible for their antibiotic activity, coupled with the discovery of the structure-function relationship. The prior patent had not disclosed the structure-function relationship, and although species A would anticipate the broad genus claim in the absence of the proviso, the proviso does not result in a lack of unity of invention among the remaining members of the genus.

Note that if the earlier patent had identified the structure-function relationship in respect of species A, it would imply a lack of unity of invention *a posteriori* since the role of the functional group in providing antibiotic activity would have been known.

14.08.08 Additional examples

As noted in 14.04, the Canadian standard for unity of invention is equivalent to that under the *Patent Cooperation Treaty*.

Additional examples helpful for understanding unity of invention can be found in sections 10.20 to 10.59 of the *PCT International Search and Preliminary Examination Guidelines*, available on the web site of the *World Intellectual Property Organization*.[19]

14.09 Right to file a divisional application

November 2013

In accordance with subsections 36(2) and 36(2.1) of the *Patent Act*, where an application (the "original application") describes more than one invention, an applicant may file a divisional application to protect described inventions other than the *one invention only* to which the original application's claims were directed or, as the case may be, to which the original application's claims were limited.

In accordance with subsections 36(2), 36(2.1) and 36(3) of the *Patent Act*, a divisional application must be filed before the original application either grants to patent or, where the original application has been abandoned, the period to reinstate it expires.

Only an applicant may file a divisional application, and only within the time period provided by statute. Although the term "applicant" is defined in section 2 of the *Patent Act* as including "an inventor and the legal representatives of an applicant or inventor", the Office takes the position that only the current owner of the application can divide it by filing a divisional application.

14.10 Filing requirements for a divisional application

April 2017

The filing of a divisional application is largely equivalent to the filing of an original application [see Chapter 5 of this manual].

When preparing the Petition (Form 3 of Schedule I of the *Patent Rules*), section 2 is completed. Only the latest owner of the original/parent application will appear in the chain of title of the divisional application. In addition, any priority requested in respect of the original application will be considered to have been requested in respect of the divisional application unless the applicant advises the Office in writing that one or more priority claims are not to be considered.[20]

In accordance with subsection 36(4) of the *Patent Act*,[21] a divisional application is considered to be filed on the same date as the original application. In accordance with subsection 99(2) of the *Patent Rules*, any maintenance fee set out in item 30 of Schedule II of the *Patent Rules* that would have been payable pursuant to subsection 27.1(1) of the *Patent Act* had the divisional application been filed on the filing date of the original application shall be paid when the divisional application is actually filed.

In accordance with subsection 96(2) of the *Patent Rules*, a request for examination of a divisional application shall be made and the fee shall be paid before the later of the five-year period after the filing date of the original application and the six-month period after the date on which the divisional application is actually filed.

The Office takes the position that the applicable fee for requesting examination of a divisional application is that set out in item 3(b) of Schedule II. This is so irrespective of whether or not the original application resulted from the national phase entry of an international application that was the subject of an international search by the Commissioner.[22]

14.11 Meaning of "original application"

November 2013

In accordance with subsection 36(4) of the *Patent Act*, a divisional application shall be deemed to be a separate and distinct application under the Act, to which the Act's provisions apply as fully as may be.

The Office takes the position that a divisional application may itself be considered an original application under section 36 of the *Patent Act* for the purposes of the filing of further divisional applications.

Thus, if a first application (the "grandparent" application) leads to a first divisional application (the "parent" application), a further divisional application (the "child" application) may be filed on the basis of either the parent application or the grandparent application.

The Office takes the position that in order for a divisional to be filed, section 36 of the *Patent Act* requires that either the parent or grandparent be eligible as an "original application", but not both. If, for example, the grandparent issued to patent or became abandoned and the period to reinstate expired, the parent application could be used to file a divisional in accordance with subsections 36(2), 36(2.1) and 36(3) of the *Patent Act*. This allows the provisions of these subsections to apply "as fully as may be" to the parent application, as provided for in subsection 36(4) of the *Patent Act*.

14.12 Time limits

November 2013

In accordance with subsection 36(4) of the *Patent Act*, a divisional application shall have the same filing date as the original application.

Unless otherwise provided for in the Act or Rules, any time limit that would apply to a regularly filed application applies to a divisional application.

Where a divisional application is filed after the expiry of the 18 month confidentiality period specified in section 10 of the *Patent Act*, the application and any documents filed in connection with it shall be open to public inspection immediately upon filing. Note that the confidentiality period of a divisional application is calculated based on the earliest filing date of any previously filed application on which a request for priority is made in respect of the divisional application. A divisional application may not have all the priority claim dates that the original application from which it was divided has.

14.13 Examination of divisional applications

November 2013

Where a request for examination has been made on a divisional application, examination will include a determination of whether the application is entitled to divisional status. The content of the specification and drawings of the purported divisional application are compared to that of the original application to determine if the claims of the divisional application are directed to a different invention than the claims of the parent, and if the divisional application contains any subject-matter that would have contravened subsection 38.2(2) or 38.2(3) of the *Patent Act* had it been added to the original application's specification or drawings by way of amendment.

Subsections 38.2(2) and 38.2(3) of the *Patent Act* provide that the specification and drawings, respectively, may not be amended to describe matter not reasonably to be inferred from the specification or drawings as originally filed ("new matter"). If the specification or drawings of a purported divisional application contain new matter with respect to the specification or drawings of the original application, the later filed application is not entirely based on the specification and drawings of the original application and is not entitled to divisional status. Simply put, something cannot be divided out of an application that could not legitimately have formed part of that application.

Similarly, if the claims in the purported divisional application are not directed to a different invention than those of the original application, the later-filed application is not a divisional application within the meaning of section 36 of the *Patent Act*.

A divisional application will be examined in its regular order according to the date on which the parent application's request for examination was made.

If, during examination, the later-filed application is considered to be not entitled to divisional status, the applicant will be notified of this conclusion and of the examiner's reasons for so concluding. Examination will proceed on the presumption that the application's filing date is the date on which the documents were actually submitted to the Office. Note that for practical reasons,[23] the electronic records of the Office will not be updated in view of this presumption unless the applicant subsequently agrees that the application is not a divisional application. An applicant may also respond to a requisition identifying the application as not entitled to divisional status by amending the application so that it becomes entitled to divisional status, or by providing arguments sufficient to convince the examiner that it is already entitled to that status.

Although the filing of an improper divisional is not, of itself, a defect in the application,[24] statements in the description asserting that the application is a divisional application will be considered inaccurate and be identified as defects under subsection 27(3) of the *Patent Act*.

Depending on the facts of the case, the purported "original application" may also be relevant prior art against the later application in the evaluation of novelty, obviousness or double-patenting. Note that if the filing of a divisional application was "directed by the Patent Office", the doctrine of double-patenting does not apply between the divisional and any of its parent or sibling applications.[25]

Endnotes for chapter 14

1. *Consolboard Inc. v. Macmillan Bloedel (Saskatchewan) Ltd.* [(1981), 56 C.P.R. (2nd), 145 (S.C.C.)] at page 168 referring to "the well-known rule that only one patent may issue for a given invention"; and *Teva Canada Ltd. v. Pfizer Canada Inc.* 2012 S.C.C. 60 at paragraph 58 affirming that "a patent shall be granted for one invention only."

2. Or of a divisional application to cover several additional inventions disclosed in the parent application, or of one or several divisional applications each to cover one of several additional inventions disclosed in the parent application.

3. *Merck & Co., Inc. v. Apotex Inc.* 2006 FC 524 at paragraph 203. Hughes J. also noted at paragraph 197 that "[d]uring the pendency of an application or several applications, the procedures to be followed are the prerogative of the Patent Office".

4. *Libby-Owens-Ford Glass Co. v. Ford Motor Co.* [(1970), 62 C.P.R. (1st), 223 (S.C.C.)] at pages 230-231, *Ciba-Geigy AG v. Commissioner of Patents* [(1982), 65 C.P.R. (2nd), 73 (F.C.A.)] at page 79

5. *Sociéte des Usines Chimiques Rhone-Poulenc et al. v. Jules R. Gilbert Ltd.* [1966] Ex. C.R. 59 at paragraphs 6-8

6. In view of this, some content in this chapter mirrors or has been adapted from text found in the *PCT International Search and Preliminary Examination Guidelines* published by the *World Intellectual Property Office* (Geneva, 2011).

7. Article 27(1) *PCT* states: No national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations.

8. *Teva* (supra at 1) at paragraph 64

9. For an example of corresponding elements, see section 10.29 of the *PCT International Search and Preliminary Examination Guidelines* (supra at 6).

10. This example is adapted from the example provided in section 10.23 of the *PCT International Search and Preliminary Examination Guidelines* (supra at 6).

11. This example is adapted from the example provided in section 10.26 of the *PCT International Search and Preliminary Examination Guidelines* (supra at 6).

12. The conclusion reached in section 10.43 of the *PCT International Search and Preliminary Examination Guidelines* (supra at 6) can be understood in this light, presuming that a single line of reasoning cannot soundly predict why the various classes of herbicide B work with A to achieve the inventive result.

13. See also the *PCT International Search and Preliminary Examination Guidelines* (supra at 6) at 10.42.

14. The conclusion reached in section 10.58 of the *PCT International Search and Preliminary Examination Guidelines* (supra at 6) can be understood in this light, since compounds X, Y and Z do not share a structural feature responsible for their activity. It must be presumed that X, Y and Z are not members of a recognised class of compounds.

15. Due regard should be given to the nature of the synthesis in performing this evaluation. The relationship of the structure of an intermediate to the final product will be quite different in, for example, a convergent synthesis than in a divergent synthesis, or in a ring-closing or rearrangement reaction than in an addition reaction. See also the *PCT International Search and Preliminary Examination Guidelines* (supra at 6) at 10.18(f).

16. See the *PCT International Search and Preliminary Examination Guidelines* (supra at 6) at 10.18(e).

17. This example is loosely based on the *PCT International Search and Preliminary Examination Guidelines* (supra at 6) at 10.47, which provides specific chemical structures to illustrate the same point.

18. A method for preparing a product would usually be considered to render the product it produces obvious, and there could consequently be an appearance of double-patenting if claims 2 and 3 appeared in different applications.

19. *PCT International Search and Preliminary Examination Guidelines* (supra at 6).

20. Note that where the applicant has made a request in section 4 of the Petition for fewer priority documents than requested for the original application, only those priority claims requested in section 4 will be considered to have been made in respect of the divisional application.

21. An equivalent provision exists for applications filed prior to October 1, 1989, under subsection 36(4) of the *Patent Act* as it read immediately before that date.

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22. This interpretation is consistent with the provisions of subsection 36(4) of the *Patent Act* and of subsection 58(10) of the *Patent Rules* (which provides that an international application can only become one national phase application).

23. Many time periods are calculated from the assigned filing date. Prematurely changing the electronic records of the Office may result in confusion and potential risks to the applicant.

24. *Merck* (supra at 3) at paragraph 203

25. *Consolboard* (supra at 1) at page 169

Chapter 15

Anticipation, Obviousness and Double-Patenting

15.01 Anticipation – June 2016

The requirement that an invention be novel finds its basis in the definition of *invention* in section 2 of the *Patent Act* – "any new [...] art, process, machine, manufacture or composition of matter or any new and useful improvement in any art, process, machine, manufacture or composition of matter".[1]

In order for an invention to be novel, it must be established that individual disclosures in the prior art do not anticipate the claimed invention.

Whether a given disclosure is considered to be prior art is governed by section 28.2 of the *Patent Act*. Although any public disclosure of information may be considered in principle, for practical reasons the assessment is almost exclusively performed on the basis of written disclosures.

Anticipation is assessed on a claim-by-claim basis by asking whether the prior disclosure, when understood by the person skilled in the art in light of their common general knowledge, provides both a description of the claimed invention (disclosure) and sufficient instructions to enable the invention to be practised (enablement).[2]

The comparison of the claimed invention to the prior disclosure is based on a comparison of the essential elements of the claim, properly construed, to the prior art.[3] Elements that are not required in order for the invention to solve the problem the inventors set out to address need not be disclosed in the anticipatory prior art. Furthermore, an invention is considered to have been previously described where the subject-matter previously disclosed would, if performed, infringe the later claim.[4]

A prior disclosure is considered to be enabling for the purpose of anticipation if the person skilled in the art, where necessary through trial and error experimentation that is neither inventive nor an undue burden, can operate the disclosed invention successfully.[5]

15.01.01 Prior art when assessing anticipation

Section 28.2 of the *Patent Act* defines what disclosures may be considered for the purpose of assessing anticipation. In summary, this section establishes: a *grace period* of one year prior to the filing date of an application during which disclosures originating from the applicant are excluded as prior art; third party disclosures anywhere in the world before the application *claim date* as prior art; and the conditions respecting first-to-file when a co-pending Canadian application filed by a person other than the applicant is prior art.

Pursuant to section 63 of the *Patent Rules*, an international application (i.e. one filed under the *Patent Cooperation Treaty*) is not considered to be a Canadian application for the purposes of *first-to-file* anticipation (paragraphs 28.2(1)(*c*) and (*d*) of the *Patent Act)* unless it has entered the national phase. Section 59 of the *Patent Rules* provides that once an international application enters the national phase to become a PCT national phase application, it is deemed to be an application filed in Canada.

In accordance with subsection 28.2(2) of the *Patent Act*, a Canadian application that is withdrawn before being opened to public inspection is considered, for the purposes of paragraphs 28.2(1)(*c*) and (*d*), never to have been filed. Consequently, such an application is not eligible as *first-to-file* prior art. Any Canadian application may be eligible as prior art under 28.2(1)(*c*) or (*d*) despite having been withdrawn after being opened to public inspection, even where it has been abandoned or refused.

15.01.01*a* Self-anticipation

Paragraph 28.2(1)(*a*) of the *Patent Act* provides that

The subject-matter defined by a claim in an application for a patent in Canada (the "pending application)" must not have been disclosed (a) more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant, in such a manner that the subject-matter became available to the public in Canada or elsewhere[.]

This provision defines a public disclosure made by the applicant or by a person who obtained their knowledge directly or indirectly from the applicant more than one year before the filing date of the application as prior art for the assessment of anticipation, but excludes this disclosure as prior art if it was made in the one year *grace period* preceding the *filing date*. [See 15.04].

15.01.01*b* Third party anticipation

Paragraph 28.2(1)(*b*) of the *Patent Act* provides that

The subject-matter defined by a claim in an application for a patent in Canada (the "pending application") must not have been disclosed

> *(b) before the claim date by a person not mentioned in paragraph (a) in such a manner that the subject-matter became available to the public in Canada or elsewhere[.]*

This provision defines any public disclosure made by a third party (i.e. by a person other than the applicant or a person who obtained their knowledge directly or indirectly from the applicant) as prior art for the assessment of anticipation if it was made before the *claim date* [see 15.03].

15.01.01*c* First-to-file anticipation based on filing-date

Paragraph 28.2(1)(*c*) of the *Patent Act* provides that

The subject-matter defined by a claim in an application for a patent in Canada (the "pending application") must not have been disclosed

> *(c) in an application for a patent that is filed in Canada by a person other than the applicant, and has a filing date that is before the claim date[.]*

This provision exists to give effect to *first-to-file* considerations, and allows a Canadian patent application that was not open to public inspection as of the subject application's claim date and which would consequently not be citable under paragraph 28.2(1)(*b*) of the *Patent Act* to nevertheless be considered for the purpose of anticipation. Note that the entire content of the earlier application is considered in assessing anticipation. The analysis is not limited by the matter claimed in the earlier application.

This provision defines a Canadian co-pending patent application, made by a third party, not open to public inspection as of the subject application's claim date and having a filing date earlier than the pending application claim date as prior art for the assessment of anticipation of the pending application. Paragraphs 28.2(1)(c) and (d) effectively establish Canada's first-to-file regime.

Where the applicability of a Canadian application as prior art under paragraph 28.2(1)(*c*) depends on the validity and extent of the priority claim of the application being examined, the examiner should obtain and verify the validity of the priority document.

15.01.01*d* First-to-file anticipation based on priority date

Paragraph 28.2(1)(*d*) of the *Patent Act* provides that

The subject-matter defined by a claim in an application for a patent in Canada (the "pending application") must not have been disclosed

> *(d) in an application (the "co-pending application") for a patent that is filed in Canada by a person other than the applicant and has a filing date that is on or after the claim date if*
>
> *(i) the co-pending application is filed by*

> *(A) a person who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for Canada an application for a patent disclosing the subject-matter defined by the claim, or*
> *(B) a person who is entitled to protection under the terms of any treaty or convention relating to patents to which Canada is a party and who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for any other country that by treaty, convention or law affords similar protection to citizens of Canada an application for a patent disclosing the subject-matter defined by the claim,*
>
> *(ii) the filing date of the previously regularly filed application is before the claim date of the pending application,*
>
> *(iii) the filing date of the co-pending application is within twelve months after the filing date of the previously regularly filed application, and*
>
> *(iv) the applicant has, in respect of the co-pending application, made a request for priority on the basis of the previously regularly filed application.*

This provision expands the definition of prior art for the assessment of anticipation of a pending application to include Canadian co-pending applications not open to public inspection as of the subject application's claim date and having a claim date earlier than the pending application claim date.

The provision requires that the co-pending Canadian application have a validly claimed priority date that precedes the claim date of the application being examined. The content of the priority document of the co-pending application should be reviewed by the examiner to ensure that the subject-matter anticipated by the co-pending application is disclosed in its priority document. The assessment is based on the entirety of the information benefiting from the priority date, and is not further limited by the claims.

15.01.02 Assessing anticipation

The test for anticipation, as set out by the Supreme Court in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.* 2008 SCC 61, requires that a single disclosure both disclose and enable the claimed invention.[6] The approach taken by the person skilled in the art in reading and applying the prior art differs slightly when assessing the two parts of the test.

The first part of the test for anticipation asks whether a single prior teaching discloses the same invention that has been claimed in the application under consideration (or, where a claim encompasses several embodiments, of at least one operating embodiment of the claimed invention). In reading the prior disclosure to understand the matter it describes, the skilled person[7] is "taken to be trying to understand what the author of the description [in the prior patent] meant".[8] The prior disclosure is read in the same informed and purposive manner as the application itself, so as to fairly interpret its teachings,[9] as if being read by the person skilled in the art at the *claim date* of the claim under consideration.[10] The disclosure does not have to be an "exact description" of the claimed invention. The disclosure must be sufficient so that when read by a person skilled in the art willing to understand what is being said, it can be understood "without trial and error".[11] Even if the prior disclosure uses quite different terms to describe its subject-matter, "if carrying out the directions contained in the prior inventor's publication will inevitably result in something being made or done which [...] would constitute an infringement" of a claim being examined, the prior disclosure describes the same invention.[12]

If the prior teaching does disclose the claimed invention, the next part of the test must be evaluated. That is, does the prior disclosure enable the disclosed invention to be operated without inventive effort or undue experimentation? [See Chapter 9 of this manual as it relates to disclosure]. At this stage, the person skilled in the art "is assumed to be willing to make trial and error experiments to get [the invention] to work".[13] Note that enablement does not mean that the earlier invention was actually put into practice, but simply that the earlier disclosure was sufficient to enable the person skilled in the art to build, operate or use the invention. If, on a fair and balanced reading of an earlier disclosure, it is unclear whether the disclosure is enabling of the claimed invention, the examiner must set forth the reasons for considering that the disclosure is, in fact, enabling. In contrast, where an applicant asserts that inventive effort or an undue burden would be required to operate an invention in view of an earlier disclosure, this should be supported by reasoned arguments and, as appropriate, by relevant facts.

While particular expressions of the test for anticipation have been provided by various Courts, a common thread is that the prior teaching has to anticipate "for [the] purpose of practical necessity",[14] implying that the test for anticipation is based on practical considerations rather than theoretical ones.[15] The test has been described as asking whether the prior art document gives "information which for the purpose of practical utility is equal to that given by the subject" application,[16] and similarly as asking whether the prior disclosure would allow the person skilled in the art to understand "and be able practically to apply the discovery without the necessity of making further experiments and gaining further information before the invention can be made useful".[17]

In many circumstances, the concept of "reverse infringement" can be used to assess anticipation.[18] Based on the principle that "what amounts to infringement, if posterior, should, as a general rule, amount to anticipation, if anterior",[19] anticipation by reverse infringement asks "if the earlier disclosure were to be put into practice, would it infringe the later claims"?[20]

While the jurisprudence describes the approach to anticipation using various expressions relevant to the facts of the cases then under consideration, ultimately it is important to bear in mind that the actual requirement to be satisfied is simply that provided in section 28.2 of the *Patent Act*. At its simplest, the assessment of anticipation can be reduced to this: the subject-matter of the claim being examined is analysed in order to identify the elements that are essential to the applicant's proposed solution to the problem being addressed by the application. The prior art is analysed to determine if it discloses and enables the use of the same elements (whether or not disclosed in the same terms) in a form suitable for the same purpose as the claimed matter. If so, the prior disclosure anticipates the later claimed subject-matter.

In performing this analysis, it may be necessary to determine whether claimed elements function in combination to produce a unitary or synergistic result. Where different elements or sets of elements in a claim operate independently of each other to produce distinct results, then the two do not form a proper combination, but rather define an aggregation. In such a case, the removal of one element would have no effect on how the remaining elements function. Where a claim is construed to define two or more collocated but distinct inventions, each invention should be individually assessed for anticipation. In such cases, a defect under section 28.2 of the *Patent Act* should not be raised unless all of the inventions are anticipated; if at least one invention is novel, the claimed subject-matter will not have been previously disclosed.

In assessing anticipation, it may also be determined that a claim encompasses many different operating embodiments. The claim will be anticipated if any one working embodiment is disclosed and enabled by the prior art.[21]

> *Example:*
>
> An application is directed to improved methods of preparing rigid polyurethane foams with good insulating values. The application discloses that the inventors set out to improve the insulating values of rigid polyurethane foams by preparing them in the presence of a blowing agent comprising a perfluorocycloalkane and a straight-chain alkane in specific ratios. The application teaches that water may be used as a co-blowing agent.
>
> Canadian application D1, filed by a third party before the claim date of the application but published later, discloses the use of a blowing agent falling within the ranges disclosed and claimed in the application in the preparation of rigid polyurethane foams. D1 is silent as to whether water should be used as a co-blowing agent. Because of its filing and publication dates, D1 is relevant for *first-to-file* anticipation under paragraph 28.2(1)(*c*) of the *Patent Act* but may not be considered when assessing obviousness.

Claim 1:

A method for producing a rigid polyurethane foam, comprising the step of contacting a polyol and an isocyanate in the presence of a blowing agent, wherein the blowing agent comprises a perfluorocycloalkane and a straight-chain alkane in a ratio of x:y and wherein the blowing agent comprises 0.05 to 0.95 wt.% water as a co-blowing agent.

Analysis:

Person of ordinary skill in the art (POSITA)

The POSITA is a chemist knowledgeable in the field of rigid polyurethane foams, including their properties and how to prepare them.

Common General Knowledge (CGK)

It is common general knowledge that foams with good insulating properties can be prepared in the presence or absence of water as a co-blowing agent. Prior art documents D2 to D5 are representative of the CGK of the POSITA, all relate to rigid polyurethane foams prepared by related blowing agents, and further disclose that foams with good insulating properties can be prepared in the presence or absence of water as a co-blowing agent. Furthermore, these documents note that water is usually present in small quantities due to the hydrophilic nature of the polyol component used to prepare the foams.

The Problem

It is clear from the description that the problem to be solved was how to improve methods of preparing rigid polyurethane foams having good insulation values.

The Solution

The solution as detailed in the description is to prepare the rigid polyurethane foams in the presence of a blowing agent comprising a perfluorocycloalkane and a straight-chain alkane in specific ratios.

What are the essential elements?

In order to solve the problem of preparing rigid polyurethane foams having good insulating values, the following elements of the claim are considered essential:

- contacting a polyol and an isocyanate

- in the presence of a blowing agent comprising perfluorocycloalkane and a straight-chain alkane in specific ratios.

The following element is non-essential to achieving the proposed solution:

- the use of 0.05 to 0.95 wt. % water as a co-blowing agent.

Although the claimed method recites the use of water as a co-blowing agent, it is clear that the common general knowledge of the person skilled in the art includes the knowledge that rigid foams with good insulating properties can be prepared in the presence or absence of water as a co-blowing agent. This is consistent with the teachings of the application's description, which discloses that water "may" (not "must") be present, and which does not disclose any specific new results arising from the presence of water. The person skilled in the art would understand that the presence of water is not an essential element of claim 1.

Is the claim anticipated?

Yes, based on a comparison of the elements essential to solve the problem the inventors set out to address, the method of claim 1 is anticipated by the enabling disclosure of D1 under the *first-to-file* provisions of paragraph 28.2(1)(*c*) of the *Patent Act*.

15.01.03 Anticipation by prior sale or use

Although the majority of prior art consists of written disclosures, the sale or use of an invention can also be relevant prior art if it effectively provides an enabling disclosure of the application's claimed subject-matter prior to the claim date of the pending application.[22]

To be considered to have disclosed the claimed invention, the prior sale or use must provide to the person skilled in the art information sufficient to comprehend the invention.[23] "The use of a product makes the invention part of the state of the art only so far as that use makes available the necessary information."[24] The information made available must be such that if the person skilled in the art were to write down that information, they would have drafted a clear and unambiguous description of the claimed invention.[25] Disclosure may be made if the public has the "opportunity to access the information that is the invention".[26]

As was noted in *Baker Petrolite Corp. v. Canwell Enviro-Industries Ltd.*, in determining whether a publicly available product anticipates a claimed invention, the ability of the person skilled in the art to reverse engineer the product "in accordance with known analytical techniques" may be relevant.[27] What is required for this consideration is the ability to reverse engineer without inventive effort; it is not necessary to establish that the product was actually reverse engineered.[28]

In considering whether anticipation by prior sale or use of an invention has occurred, the *grace period* provided for in paragraph 28.2(1)(*a*) of the *Patent Act* applies in respect of any making available of the invention by the applicant or by a person who obtained the relevant knowledge directly or indirectly from the applicant.

15.01.04 Implicit or inherent disclosure

An enabling disclosure is considered to disclose everything that would inevitably or necessarily occur or be done by a person practising the invention. Old and known subject-matter is not rendered novel simply by disclosing and claiming a feature which is inherently (i.e. necessarily present) or implicitly (i.e. suggested but not directly expressed) found in the prior art.[29] The concepts of inherent and implicit disclosure are related.

Inherent features of a disclosed invention include properties and characteristics of the elements of the invention, such as the ductility of a metal used in a part in a machine, the mechanism of action of a drug taken to treat a disease, or the thermoplastic properties of a polymer.

Implicit features include those things that a person skilled in the art would, in view of their common general knowledge, necessarily understand to be part of what one would do in order to operate the disclosed invention. If a chemical process calls for 'distillation at reduced pressure' without further elaboration, the use of some means for reducing the pressure to below atmospheric is implicit. If a watch band is to be assembled using parts that interact to give the band greater flexibility, the use of attachment means to hold the parts together would be understood by the person skilled in the art and could be considered implicit in the disclosure even if no specific directions to attach the parts together were given.[30]

The mere discovery of the properties of a previously disclosed invention does not make that invention newly patentable, but where the discovery leads to a new practical application of the previous invention that new practical application may be patentable.[31]

> *Example:*
>
> Consider that a prior art document discloses a chemical compound X and how to make it, and establishes that compound X is useful in treating disease Y. Where subsequent research uncovers the mechanism of action of the compound, a claim to the use of compound X to treat disease Y via the newly discovered mechanism is not novel. Compound X inherently treated disease Y via the mechanism, and the discovery has not led to a new use for the known compound.[32] However, if the discovery of the mechanism allows one to conclude that compound X would also be useful in treating disease Z, the use of compound X to treat disease Z may be patentable.

Where features implicit or inherent in a previously disclosed invention are being considered when assessing anticipation, it is important to recognise that such features do not create a new invention if a person using the previously disclosed invention would already have achieved the benefits arising from the presence of the implicit or inherent features. This follows from the "well-known principle in Patent law that a man need not state the effect or the advantage of his invention, if he describes his invention so as to produce it".[33] The earlier invention is sufficiently disclosed even if all its advantages were not taught, and the earlier inventor "is entitled to its benefit even if he does not fully appreciate or realize the advantages that flow from it or cannot give the scientific reasons for them".[34] Performing the earlier invention would provide the benefits arising from the implicit or inherent features; under the principle of anticipation by reverse infringement [15.01.02], the earlier disclosure would be anticipatory.

Where a conclusion of anticipation requires the presence of an inherent or implicit feature, it is necessary for the examiner to clearly explain the basis for concluding that the feature is implicit or inherent to the matter of the prior disclosure. Where such a conclusion is supported by secondary references, the date of publication of these references is not important.

> *Example:*
>
> In the field of respiratory diseases, the use of a powdered drug C is well known.
>
> An applicant files an application A, which describes a powder inhaler capable of aerosolizing and delivering powdered medicament to a recipient. Their specification describes and illustrates the inhaler as having means for varying airflow volume and resistance and notes that adjustments thereto may be made for delivering unspecified powdered medicaments. No indication is made as to the specific airflow properties of the inhaler but feature Z is illustrated.
>
> More than 12 months after the publication of application A, the applicant files application B, which describes a delivery-efficacy testing regimen for the inhaler claimed in application A. Application B does not describe any inventive medicament, but does refer to drug C. No modifications to the inhaler are disclosed in application B.
>
> Claims of application B:
>
> 1. A dry powder inhaler for delivering a powdered drug, comprising feature Z and having a delivery efficiency of at least W wherein the inhaler has a flow resistance of X at a flow rate of Y.
>
> 2. The dry powder inhaler according to claim 1 wherein the powdered drug is C.

Analysis: Application B discloses that the dry powder inhaler described in application A was used for the applicant's trials, and does not describe any modifications made to the inhaler. It must be concluded that whenever the dry powder inhaler of application A is used, it will have the delivery efficiency, flow resistance and flow rate defined in the claim. These are merely inherent properties of a dry powder inhaler as described in application A. Inclusion of these properties in the claim of application B does not direct claim 1 to a different dry powder inhaler than the one disclosed in application A. Claim 1 is therefore anticipated.

Claim 2 defines the dry powder inhaler of claim 1 wherein the drug that will be delivered is the well-known drug C. Since no adaptation of the inhaler is, in view of application B, required for it to deliver drug C, the claim remains directed, simply, to the inhaler disclosed in application A and is anticipated. Defining that the inhaler is capable of delivering drug C merely specifies one of its inherent abilities.

15.01.05 Anticipation based on related teachings

Anticipation assesses whether a single prior disclosure both revealed the invention in a claim being examined and enabled a person skilled in the art to operate it.

In some limited situations, a single prior disclosure can comprise teachings in more than a single document. This may occur where a primary source of information makes explicit reference to specific teachings in a secondary source, thereby making clear to the skilled reader that the teachings of the secondary source are to be relied on in order to understand or complete the disclosure of the invention in the primary source.

In order to consider multiple sources of information to comprise a single disclosure, there must be an unambiguous relationship between the two sources. References in one source that merely mention the other are not sufficient to establish such a relationship. Rather, the first source must direct the reader to use the teachings of the second source for the purposes of understanding and operating the invention.

15.02 Obviousness – June 2016

The requirement that an invention be inventive was, prior to October 1, 1996, recognised judicially as inherent to the definition of *invention*[35] but is now more formally reflected in the *Patent Act*.[36] Ingenuity is tested by determining whether the claimed invention is obvious (i.e. uninventive) when considered by a person skilled in the art in light of their common general knowledge and the state of the art as a whole.[37] In contrast to the approach for assessing anticipation [see15.01.02], the evaluation of obviousness allows for a consideration of the combined teachings of multiple prior art documents that the person skilled in the art would discover in a "reasonable and diligent search".[38]

The use of the term "obvious" in section 28.3 of the *Patent Act* has not changed the inherent requirement that an invention be the result of ingenuity.[39] The courts have noted that "obviousness is an attack on a patent based on its lack of inventiveness"[40] and "[t]he courts have chosen to define 'lack of inventiveness' rather than 'inventiveness' and have called it 'obviousness' ".[41]

Obviousness is assessed on a claim-by-claim basis by asking whether the claimed invention is obvious (or uninventive) when considered by the person skilled in the art in light of their common general knowledge and the state of the art as a whole.
As with the assessment of anticipation, the assessment of obviousness is based on the elements which would be recognised by a person skilled in the art as providing the solution to a given problem. There is nothing inventive in adding elements to a claim that are irrelevant to the invention's successful operation.

To be considered obvious, the teachings present in the prior art must be sufficient so that, if combined, they would lead to the claimed invention (or to a working embodiment within the claim). Furthermore, it must be obvious (i.e. uninventive) to combine the necessary teachings so as to arrive at the claimed invention.

15.02.01 Prior art when assessing obviousness

Section 28.3 of the *Patent Act* defines what disclosures may be considered for the purpose of assessing obviousness. Although any public disclosure of information may be considered in principle, for practical reasons the assessment is almost exclusively performed on the basis of written disclosures. In summary, this section provides for a one-year *grace period* with respect to disclosures by the applicant before the *filing date* and allows any third party disclosure anywhere in the world made prior to the *claim date* to be considered.

15.02.01*a* Obviousness and prior disclosures by the applicant

Paragraph 28.3(*a*) of the *Patent Act* provides that

The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to

> *(a) information disclosed more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant in such a manner that the information became available to the public in Canada or elsewhere.*

This provision defines public disclosures by the applicant, or by a person who obtained their knowledge directly or indirectly from the applicant, made more than one year before the filing date of the application as prior art for the assessment of obviousness, but excludes these disclosures as prior art if made in the one year *grace period* preceding the *filing date*. For further information on *grace period* see 15.04.

15.02.01*b* Obviousness and third party disclosures

Paragraph 28.3(*b*) of the *Patent Act* provides that

The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to

> *(b) information disclosed before the claim date by a person not mentioned in paragraph (a) in such a manner that the information became available to the public in Canada or elsewhere.*

This provision defines any public disclosure made by a third party (i.e. by a person other than the applicant or a person who obtained their knowledge directly or indirectly from the applicant) as prior art for the assessment of obviousness if it was made before the *claim date* [see 15.03].

15.02.02 Assessing obviousness

Obviousness is assessed from the viewpoint of the person skilled in the art, in light of their common general knowledge and the state of the art as it was on the claim date. For a claimed invention to satisfy the requirement of section 28.3 of the *Patent Act* there must be present that "characteristic or quality" (i.e. that "scintilla of invention necessary to support the patent"[42]) which serves to elevate the matter of the claims from mere workshop improvement to real invention.[43]

Although various tests have been expressed for assessing obviousness, the inquiry is not well served by attempting to rigidly apply any one test in all circumstances.[44] It is important to address the question in an informed way and the Supreme Court has endorsed a four-step analysis for this purpose, wherein the first three steps frame the inquiry and the fourth step is to ask the pertinent question.

The four steps in the analysis were set out by the Court in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.* as:[45]

(1) (a) Identify the notional "person skilled in the art";
(b) Identify the relevant common general knowledge of that person;
(2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;

(3) Identify what, if any, difference exists between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;

(4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

The Supreme Court's admonition against attempting to apply any one test in all circumstances refers specifically to the question asked at step 4.

The *Sanofi* four-step analysis will typically be done intuitively and automatically by an examiner. Where there appears to be a disagreement between the examiner and applicant(s) as to whether or not a claim is obvious, the *Sanofi* four-step analysis should be set out in a report. This analysis must be set out in a pre-final or *Final Action* report.

To inform the first step of the *Sanofi* four-step analysis, guidelines for the identification of the person skilled in the art and of the common general knowledge follow. It should be kept in mind that the person skilled in the art and the common general knowledge of said person are considered in many aspects of examination and the following discussion is useful in this regard.

15.02.02*a* Person skilled in the art (Step 1(a))

The person skilled in the art is a fictitious construct that represents an average worker competent in the field or fields relevant to the invention.[46] The person skilled in the art can represent an individual, or a team of individuals whose conjoint knowledge is relevant to the invention in suit.[47]

The person skilled in the art is considered to be competent; a logical but unimaginative worker in the field,[48] who is neither a dull-witted incompetent nor a creative, intuitive expert.[49] In a highly technical field, the person skilled in the art may be presumed to have expert-level knowledge and skills.[50] The skilled person need not be a manufacturer or designer, but must understand the problem to be overcome, have knowledge of means to address the problem and the likely effect of using the means.[51] Furthermore, the person skilled in the art is reasonably diligent in keeping up with advances in the field or fields of relevance to the invention,[52] and has the advantage of being multilingual and thereby being able to comprehend prior art in any language.[53] Note that the person skilled in the art may have knowledge from outside the field of the invention, although it should not be presumed that they would.[54] In this context, the nature of the problem being addressed by the alleged invention may be helpful in defining the skilled person.

The person skilled in the art is presumed to read prior disclosures in the same manner as the specification of the application itself. That is, with a mind willing to understand[55] and desirous of success.[56] In understanding the significance of the prior art, they may apply teachings from one source to another setting or even combine teachings.[57]

During examination, the person skilled in the art is relevant in many contexts. It is important to recognise that there is only a single description of the person skilled in the art for a given alleged invention. Nevertheless, the common general knowledge of the person skilled in the art will depend on the date at which an understanding of the application is required.[58] Note that in some circumstances, this can require the person skilled in the art to rely on knowledge which, while generally accepted at the relevant date, was later shown to be wrong.[59]

Depending on the specifics of a given case, it may be necessary to explicitly identify the person skilled in the art. It should be stressed that this is not necessary where the nature of the person skilled in the art does not appear to be under debate or where it is unlikely to impact on any conclusions as to patentability.

Where the specific nature of the person skilled in the art is relevant for resolving an issue during examination, the examiner will determine who this person is by reference to the field or fields relevant to the invention and will consider comments by the applicant in the determination. The person skilled in the art may be ascertained from the language of the specification of the application.[60] Attributes such as proclivity for engaging in research or experimentation may help form the profile of the skilled person.

Although the characterisation of the person skilled in the art should be done carefully,[61] it should also be done with a certain degree of generalisation.[62] During examination, an examiner must attempt to interpret the application and the prior art using the appropriate knowledge that the person skilled in the art would have possessed at the claim date. Specific details such as the skilled person's exact educational background or length of work experience are typically unnecessary and have the potential to be misleading or overly restrictive; precise definitions of the skilled person should therefore be avoided.

15.02.02*b* Common general knowledge (Step 1(b))

"Common general knowledge means knowledge generally known by persons skilled in the relevant art at the relevant time."[63] The common general knowledge in a field has been described as the knowledge that emerges as common themes from the "forest of art", and which becomes commonly known to the ordinary person skilled in the art.[64] This knowledge undergoes continuous evolution and growth.[65]

The common general knowledge distinguishes the body of information that is widely recognised from that which is simply publicly available. Individual disclosures may become common general knowledge, but only when they are generally known and regarded as a good basis for further action.[66] At the same time, some information that forms part of the common general knowledge may not have been written down at all.

Where the common general knowledge in a field becomes relevant for the purposes of examination, examiners may refer to information they believe to have been common general knowledge as of the *claim date*. Unless it becomes evident through the applicant's comments that the nature of the common general knowledge is not common ground and is reasonably in dispute, an examiner need not identify documents establishing the common general knowledge.

Where it is appropriate or necessary to establish the common general knowledge in a field (for example where the examiner and applicant disagree as to the common general knowledge), this can be done by citing established reference works (such as textbooks, review articles, handbooks, etc.) or by demonstrating commonality of certain knowledge in a number of disclosures in the field. The common general knowledge at a certain date can be confirmed by subsequent publications,[67] or by showing that the knowledge had been accepted in the field over a period of time. Statements in the application's description that describe certain information or knowledge as commonly known may be relied upon, without verification, as establishing aspects of the common general knowledge; an applicant will be bound to such comments.[68]

15.02.02*c* Identifying the inventive concept (Step 2)

The inventive concept of a claim is not necessarily the same as the essential elements gleaned following a purposive construction analysis. Construing the inventive concept for the purpose of the obviousness analysis is a separate exercise from claim construction, meaning that the construction of the claims is not determinative of the inventive concept.[69]

Purposive construction is used to determine the essential elements of a claim i.e., those elements that provide the solution to the problem that the inventor set out to solve. In contrast, the inventive concept comprises the feature or features of the claim that appear to be inventive over the common general knowledge and/or which the applicant appears to consider inventive. It should be remembered that the identification of the inventive concept should be based on a reading of the specification as a whole from the perspective of the person skilled in the art, in light of their CGK. The inventive concept may be determined to be a combination of the same essential elements identified during the purposive construction analysis and will generally include at least some of the essential elements, but it might not include all the essential elements of the claim as construed.

Purposive construction is outlined in Chapter 13 of this manual.

15.02.02*d* Identifying the differences between the inventive concept and the state of the art (Step 3)

At step 3 of the obviousness analysis, the inventive concept of the claim in step 2 is compared to the state of the art to determine whether, or to what extent, an equivalent or similar solution to the problem being addressed by the applicant was known at the claim date. The state of the art refers to the information available to the person skilled in the art in accordance with section 28.3 of the *Patent Act*, and generally will be identified by reference to specific prior art documents that would have been discovered in a "reasonable and diligent search".

Should there be no difference between the inventive concept of the claim and the state of the art, the claim is most likely defective for being anticipated or obvious. For example, a claim may be anticipated where there is no difference between the inventive concept of a claim and only one prior art disclosure that is cited as state of the art, provided that the prior art disclosure is enabling. In cases where the prior art disclosure is not enabling, the claim may not be anticipated but may still be obvious. A claim may also be obvious where more than one state of the art document is required to arrive at the inventive concept.

Where differences exist between the inventive concept of the claim and the state of the art, it must be determined whether these differences would have been obvious to the person skilled in the art as of the claim date.

15.02.02*e* Do the differences constitute an inventive step? (Step 4)

Once any differences between the state of the art and the inventive concept of the claim or the claim as construed have been identified, it must be determined whether the subject-matter of the claim is obvious or is the result of inventive ingenuity. This must be done without presupposing that the specific problem addressed by the inventors was recognised in the prior art, so as to avoid adopting an improper "hindsight" perspective. Where the existence or nature of a problem was unobvious, the act of identifying the problem may inform the inventive concept.

As noted above, various tests have been articulated in the jurisprudence in order to answer this question, and the Supreme Court has cautioned that no single expression of this test is likely to apply to all circumstances. Although the test question may be framed taking into account the nature of the specific case in question, one must never lose sight that its purpose is to evaluate the statutory requirement of section 28.3 of the *Patent Act* and care should be taken to ensure the question is not phrased in such a way that a different standard is applied.

In answering the question at step 4, the factors to be considered include:

(i) the climate in the relevant field at the time the alleged invention was made, including not only knowledge and information available but also attitudes, trends, prejudices and expectations that would define the person skilled in the art;
(ii) any motivation in existence at the time of the alleged invention to solve a recognised problem in the field of the invention; and
(iii) the time and effort involved in the invention[70]

It should also be remembered that "the inventive ingenuity necessary to support a valid patent may be found in the underlying idea, or in the practical application of that idea, or in both. It may happen that the idea or conception is a meritorious one, but that once suggested, its application is very simple. Again, it may be that the idea is an obvious one, but that ingenuity is required to put it into practise. Or, again, the idea itself may have merit and the method of carrying it into practise also requires inventive ingenuity".[71]

Where the problem to be solved was already recognised in the art, it may be appropriate to inquire only into whether inventive ingenuity was required to conceive of the claimed solution and put it into practice. Where, however, the problem or its underlying cause was not previously recognised or understood, there may be an invention even where the proposed solution to the newly identified problem would have been immediately apparent to the person skilled in the art. Inventive ingenuity, however, does not exist if the alleged problem never existed and was simply an artificial obstacle or "straw man" developed to imply inventiveness in the proposed "solution".[72]

The assessment of obviousness is approached by considering the prior art as a whole, and the teachings of several documents may be combined in order to show why the claimed subject-matter is not the result of inventive ingenuity. When combining teachings from several documents, the relationship of the documents to each other, and to the person skilled in the art, must be considered. An explanation as to why it was obvious to combine the teachings may be necessary in situations where it is not self-evidently so. This may be given, for example, by establishing why a motivation to combine the teachings in the cited documents exists, whether based on the teachings of the documents themselves, on the common general knowledge or trends in the field of the invention.

Where a document from outside the field of the invention is relied upon in the analysis, the need to explain why it would be obvious to apply the teachings to the field of the invention is greater.

> Example of *Sanofi* four-step analysis:
>
> An application discloses a method of cleaning lead from the interior of a steam still using a high-pressure stream of water. Suitable operating parameter ranges are disclosed, encompassing those that were actually used by the inventors to successfully clean a still.
>
> The use of high-pressure water to clean surfaces has many applications, and is used in many environments. A search of the prior art reveals documents D1-D3. D1 teaches a method of removing carbon deposits from the interior of a smoke stack by sweeping a high pressure stream of cleaning fluid over the encrusted surface. D2 teaches a wet abrasion process for removing calcium deposits from

tiles, and includes illustrations of distributed and focussed spray patterns and of workers sweeping a sprayer at a surface from a distance. D3 teaches a pressure washer for cleaning barnacles off the hull of a vessel, and discloses interchangeable nozzles attachable to a wand where each nozzle produces a specific spray pattern. Each of the documents discloses operating parameters suitable for its specific environment.

Claim 1:

A method of removing lead residue from the interior of a steam still, wherein a stream of fluid from a nozzle is directed to a surface of the steam still at a velocity of between 300 and 1200 ft/s, with the nozzle held from 1-12 inches from the surface at an angle of between 15 and 45 degrees.

Analysis: The problem addressed in the application is cleaning deposits off a hard surface.

In order to determine whether the claimed subject-matter is inventive, the claim is assessed via the four step method [see 15.02.02].

(1) (a) Identify the notional "person skilled in the art":

The person skilled in this art is taken to be a technician familiar with high-pressure washing and general removal, i.e., cleaning, of deposits from surfaces.

(b) Identify the relevant common general knowledge of that person:

The common general knowledge includes an understanding of typical operating parameters for pressure-washers, suitable cleaning agents and common applications for such washers.

(2) Identify the inventive concept of the claim in question:

In this case the inventive concept includes all of claim 1: a method of removing lead residue from the interior of a steam still, wherein a stream of fluid from a nozzle is directed to a surface of the steam still at a velocity of between 300 and 1200 ft/s, with the nozzle held from 1-12 inches from the surface at an angle of between 15 and 45 degrees.

(3) Identify what, if any, difference exists between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed:

The inventive concept of the claim differs from the state of the art (D1 to D3) in specifying that the surface to be cleaned is the interior of a steam still and in establishing certain specific operating parameters.

(4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

The person skilled in the art, presented with a steam still surface requiring cleaning would arrive at the operating parameters defined in the claim without inventive ingenuity or undue burden. The use of a pressure-washer in a steam still is directly analogous to its use in the environments disclosed in D1 to D3, and uninventive in view of those disclosures. No unexpected result arises from operating the washer within the parameters defined in the claim. The subject-matter of the claim is therefore obvious.

15.02.03 Obvious to try considerations

Determining whether a claimed invention is obvious at step 4 of the obviousness inquiry may involve asking whether the claimed subject-matter is obvious because the route to the invention would have been *obvious to try*. This approach may be especially pertinent in "areas of endeavour where advances are often won by experimentation"[73] but there are no restrictions on its applicability to specific technologies.[74,]

When considering an *obvious to try* analysis, the following non-exhaustive list of factors is relevant:

1. Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identified predictable solutions known to the person skilled in the art?
2. What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?
3. Is there a motive provided in the prior art to find the solution the patent addresses?[75]

When assessing obviousness during examination, these factors may be recast as questions to be considered by the examiner:

1. Would the person skilled in the art have been aware, in view of the prior art and the common general knowledge on the *claim date*, that a limited number of predictable and identifiable solutions exist to the same or a similar problem such that they would believe that one of those solutions more or less self-evidently ought to work to solve the problem being addressed?

For the purpose of the *obvious to try* analysis, it is not necessary that a particular choice from the available solutions be immediately obvious as providing the claimed subject-matter, nor is it necessary that a particular option be best suited to providing the solution. If none of the limited number of predictable and identifiable solutions is related to the solution covered by the claimed subject-matter, the examiner may conclude that the skilled person would not have deemed the subject-matter *obvious to try*.

2. Could the person skilled in the art be expected to arrive specifically at the solution claimed, starting from the limited number of solutions conceptually identified in factor 1, without inventive step or undue burden? That is, would the solution be arrived at by routine and predictable methods, and without requiring prolonged and arduous effort?

The more difficult it is to arrive at the claimed subject-matter from the limited number of likely solutions, the less likely it is that a conclusion of *obvious to try* is appropriate. Where the person skilled in the art would need to exercise inventive ingenuity in order to solve problems for the purpose of testing the various solutions, for example, it cannot be considered obvious for the person skilled in the art to have tried that route.

In cases where the *obvious to try* test may be appropriate, the examiner will objectively determine if the exercise of inventive ingenuity or undue effort were necessary to arrive at the claimed solution. The examiner will take into account the nature of the person skilled in the art and the knowledge and the climate in the relevant field or fields at the *claim date*. The subjective experience of the inventors will not be considered relevant unless it can be established that it reflects what would have been expected of the hypothetical person skilled in the art.

3. Does the person skilled in the art, in view of the prior art, have a motive to find the solution the problem addressed by the application?

The existence of motivation, in the broadest sense, to solve problems in the field of the invention through scientific inquiry will generally not be sufficient to sustain a conclusion that the claimed invention is *obvious to try*. It will usually be necessary to show that there was a more specific motivation to work along similar lines as those pursued by the inventor. The person skilled in the art must have been motivated to conduct experiments in the area of the invention, aimed at solving the same or a similar problem to that addressed by the inventor by identifying a solution such as that defined in the claim under consideration.

The attitudes, prejudices and expectations of the person skilled in the art and their awareness of the trends in their field are relevant factors to consider in assessing subject-matter as *obvious to try*, and are assessed in light of the state of the prior art.

It should be remembered that *obvious to try* considerations are used to determine whether the subject-matter of a claim is the result of inventive ingenuity and, by consequence, is unobvious. Factors 1 to 3 might be thought of as asking whether it was obvious to search for a solution to the problem addressed by the inventors (the motivation factor) and whether the route to the claimed subject-matter was also obvious. If there was no invention in either conceiving of the solution or reducing it to a practical form, the claimed subject-matter is not the result of an inventive step and is therefore obvious.

Where the questions in factors 1 and 3 can be answered in the affirmative, and the conclusion when considering factor 2 is that the subject-matter of the claim would be arrived at by routine trials that were not prolonged and arduous, it can be concluded that the subject-matter of the claim is obvious since it would have been *obvious to try* to identify the claimed matter from among a finite number of likely solutions one of which more or less self-evidently ought to work.

Little guidance exists as to which areas of endeavour are those in which advances are often won by experimentation, although it has been commented that in such areas "there may be numerous interrelated variables with which to experiment".[76] Where there are a finite number of identified, predictable solutions known to the person skilled in the art and a motivation provided in the prior art to find the solution the application addresses, these factors can be indicative that one is in an area of endeavour where advances are often won by experimentation. The "threshold" question of whether *obvious to try* is applicable is considered to be inherently addressed when the factors of the test itself are considered.

15.02.04 Aggregations

As stated in section 15.01.02, elements that cooperate to produce a unitary result must be considered in combination when novelty is being assessed. It is not necessary for any of the individual elements of a claim to be new provided the elements are combined to produce a unitary result that is different from the sum of the results of the elements.[77] Such combinations are patentable whereas "a mere aggregation of elements is not".[78] The subject-matter of a claim is considered to be a mere aggregation if each of the elements performs its own individual function and if any one element is removed the remaining elements would continue to perform their own individual function.[79]

When an invention is merely a juxtaposition of parts or known devices, and each part or device merely functions as would be expected if it were used on its own, the assembly is not a true combination but is a mere aggregation. An aggregation of old parts cannot form the basis of a patentable invention.

An aggregation should be identified as a defect under section 28.3 of the *Patent Act* as being obvious. Separate prior art documents may be cited to show that each individual part is known in the prior art.

15.02.05 Obviousness and utility

In many cases, the ingenuity of an invention is related to its utility. This is particularly the case where some unexpected result is achieved through the subject-matter of the claim. This can arise, for example, where a known product or process is modified in some way that makes it novel and leads to the unexpected result. The unexpected result could be, for example, that the product or process becomes useful for some new purpose or provides some additional advantage when used for its intended purpose. Alternatively, the unexpected result could be that despite simplifying the known product or process (for example, by omitting parts or steps) the utility of the original product or process is retained.

Where the invention lies in discovering that a known thing has properties that make it useful for some new purpose, that mere discovery does not confer patentability on the known thing. The new use may be patented, however, if it is novel and unobvious.

Minor variations in existing inventions, such as the changing of size, shape, proportion or quality,[80] where the result is merely the doing of "the same thing in the same way, by substantially the same means, with better results, is not such an invention as will sustain a patent".[81] The substitution of a superior material for an inferior material, where the advantages of the substitution were expected, has similarly been found to be obvious.[82]

Even where the use is different, there must be something unexpected or inventive in play to support a patent. "A patent for the mere new use of a known contrivance, without any additional ingenuity in overcoming fresh difficulties is bad and cannot be supported. If the new use involves no ingenuity, but is in manner and purpose analogous to the old use, although not quite the same, there is no invention".[83]

Where a combination of parts is being considered, "[a]ll the elements being old, and the functions to be performed being identical, [it can] be patentable only if it performed the old function in some better or cheaper way than did the earlier machines - there must be a new mode of operation resulting from the combination [...]; it is not invention to combine old devices in a new machine or manufacture without producing some new mode of operation...".[84] Absent a new unitary result arising from their combination, an assemblage of known parts is merely an uninventive aggregation [see 15.02.04].

The assessment of utility and obviousness may also be somewhat interdependent where the utility of the invention must be based on a sound prediction, particularly where the information necessary to permit a person skilled in the art to soundly predict that a known thing would be useful for some given purpose forms part of the *state of the art*. Although in certain situations it may be that an invention either lacks sound prediction or is obvious, it must be remembered that the assessment of sound prediction and the assessment of obviousness are distinct tests.[85] The former is based on the applicant's own description and drawings, scientifically accepted laws or principles and the common general knowledge of the skilled person, while the latter is based on the *state of the art*.

15.02.06 Obviousness of anticipated claims

Where the subject-matter of a claim is considered to be anticipated by a prior art disclosure, it will often also be considered to be obvious. The existence of an anticipatory disclosure will typically lead to the conclusion at step 3 of the *Sanofi* obviousness analysis that there is no difference between the inventive concept of the claim and the state of the art [see 15.02.02].

Where the applicant's amendments or arguments in response to the examiner's requisition overcome the lack of novelty defect, the claim may nevertheless remain defective for obviousness.

In the interests of keeping examination efficient, examiners having identified that a claim is defective in view of the prior art need not provide separate analyses for anticipation and obviousness defects where a single analysis is applicable to both assessments. It remains permissible for both defects to be identified in a later report, particularly where the applicant's amendments or arguments have assisted in more clearly identifying any points of disagreement in respect of the applicability of the cited prior art.

When responding to an examiner's report identifying a lack of novelty, an applicant may be well served to provide comments explaining why the claimed subject-matter should be considered unobvious even if obviousness was not explicitly identified as a defect in the examiner's report. While no single test is appropriate in all cases where obviousness is a consideration, the *Sanofi* four-step analysis outlined in 15.02.02 will generally be used by the examiner. An applicant should consider this approach when formulating an argument.

Where an examiner considers that an impasse is developing in respect of the applicability of the prior art, and that the application is approaching rejection in a *Final Action*, separate analyses for anticipation and obviousness should be provided. This must be done at least one report before the *Final Action*. More information on the requirements for issuing a *Final Action* may be found in Chapter 21 of this manual.

15.03 Claim date – June 2016

In accordance with section 28.1 of the *Patent Act*, a claim's *claim date* is the earliest validly claimed priority date for that claim or, where there is no valid priority date, is the application's *filing date*.

A valid priority date is one based on an earlier regularly filed application that discloses the claimed invention and on which a claim for priority was made within the allowed time. The earlier regularly filed application may conveniently be referred to as a "priority document", and may be an earlier application filed by an eligible person in Canada or an earlier application filed by an eligible person in an eligible country. Chapter 7 of this manual details priority claims in greater detail.

In principle, each claim in an application may have a different *claim date* from all other claims, although in practice it is typical for an application to claim priority from one or two priority documents.

Where a public disclosure would be relevant prior art for the assessment of anticipation or obviousness if a claim's *claim date* is the application's *filing date*, but not relevant if the claim's *claim date* is a specific priority date, it will be necessary for the examiner to verify the content of the relevant priority document. The priority is valid only to the extent that the priority document discloses the same subject-matter as is claimed in the application. Where the scope of the teachings in the priority document and the application are different, the claim in the application may not benefit from the earlier *claim date*. Where, for example, the priority document teaches a specific embodiment and the application claims generalised subject-matter covering the specific embodiment, a claim to the generalised subject-matter may not benefit from the priority date if further support for the generalised subject-matter is not found in the priority document, whereas a claim limited in scope to the specific embodiment disclosed in the priority document would.

15.04 Grace period – September 2017

The *Patent Act* provides for a one-year *grace period* before the *filing date*, during which information that became publicly available due to a disclosure by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant, is not considered during the assessment of whether the claimed invention is novel and inventive.

As defined in section 2 of the *Patent Act,* the term *applicant* "includes an inventor and the legal representatives of an applicant or inventor". The term *legal representative* itself "includes heirs, executors, administrators of the estate, liquidators of the succession, guardians, curators, tutors, transferees and all other persons claiming through applicants for patents and patentees of inventions or through holders of certificates of supplementary protection".

In considering whether the *grace period* applies to a given disclosure of information, the prior disclosure is only protected by the *grace period* if the person making the disclosure was, or must be deemed to have been, *the applicant or a person who obtained knowledge, directly or indirectly, from the applicant* at the time the earlier disclosure was made (i.e. at the date of making available to the public, such as the date of publication or of laying open for public inspection).[86]

The *grace period* covers any prior disclosure, whether an oral disclosure such as a presentation at a conference or a written disclosure such as an article in a trade journal. Since the majority of disclosures of information relevant to patent examination are publically available documents, the applicability of the *grace period* is typically assessed by considering whether the application being examined and the prior publication share authors (e.g. whether the inventors were the authors of a prior publication) or, where the prior disclosure is a patent document, had the same applicant. It must be remembered that, in respect of domestic patent documents, the *grace period* applies when considering anticipation or obviousness, but not when assessing double-patenting.

In cases where the applicability of the *grace period* is in dispute, the applicant may provide such evidence as they consider appropriate to support a relationship between the author of the prior disclosure and the applicant.

15.05 Establishing the publication date of prior art – January 2016

In order for a prior disclosure to be considered prior art, the date at which it became available to the public must generally be known. Where the exact date on which a disclosure was made to the public is not known, the disclosure cannot be cited unless a reliable basis exists for concluding that the information was available to the public before the relevant date (i.e. claim date).

For patent documents (issued patents and applications), this information is usually known. In other cases, it may be less clear. It will usually be possible to determine the publication date of articles published by reputable journals, magazines and similar publications. In many cases, the actual date of publication will be indicated (either of the article in particular or of the issue of the publication in which it is found). In certain cases, only the month and year of publication will be identified. In such cases, it cannot be presumed that the document became available to the public before the last day of the month. Where only a year of publication is available, it cannot be presumed that the publication date was earlier than December 31 of that year.

There may be methods for establishing earlier actual publication dates, including (in the case of documents available on the internet) establishing dates of first publication via third party archiving services.

15.05.01 Verifying the validity of priority documents

In order to verify the validity of a priority document the examiner should first attempt to acquire the document from a reliable source, e.g. WIPO's PATENTSCOPE database or the International Bureau. Where the priority document is not retrievable by the examiner or where the content of a non-certified copy of the priority document has been relied upon and some question exists as to its accuracy, the applicant may be requisitioned in accordance with section 89 of the Patent Rules to provide a certified copy of the priority document.

Section 89 of the *Patent Rules* provides that

> *[w]here a previously regularly filed application on the basis of which a request for priority is based is taken into account by an examiner pursuant to sections 28.1 to 28.4 of the Act, the examiner may requisition the applicant to file a certified copy of the previously regularly filed application and a certification from the patent office in which the application was filed indicating the actual date of its filing.*

15.06 Double-patenting – September 2017

Double-patenting refers to the judicially recognised proscription against an applicant being granted more than one patent for a single invention.[87] The principles governing the doctrine of double-patenting have evolved in the jurisprudence, which now recognises two branches: "same invention" and "obviousness" double-patenting.[88]

Underlying this doctrine is the recognition by the Courts that "a second patent [can] not be justified unless the claims [exhibit] "novelty or ingenuity" over the first patent".[89] In essence, once a patent is granted for an invention, "further invention" is required to support another patent.[90]

The assessment of double-patenting, in practical terms, can be understood as a specialised evaluation of anticipation and obviousness wherein the "prior art" consists solely of one other patent by the same applicant (the "existing patent"). The assessment differs from the statutory assessment of anticipation and obviousness in two important ways:

i) the "prior art" under consideration is not citable under paragraph 28.2(1)(*a*) or 28.3(*a*) of the *Patent Act*; and
ii) only the claims of the "prior art" patent by the same applicant are considered in the assessment.

The assessment involves a comparison of the claims rather than the disclosure, as the claims define the monopoly. However, claim comparison is not done on a literal construction of the claims; claims are to be given a purposive construction based on a reading of the specification through the eyes of the skilled person, taking into account their common general knowledge. If the claims of the existing patent, when understood by the person skilled in the art in light of the common general knowledge on the *claim date* and the teachings of the specification as a whole, anticipate or render obvious the claims of the application being examined, the claims are not patentably distinct from each other. Granting both sets of claims would therefore result in double-patenting. Where it can be concluded that the claims in an application are "not patentably distinct" from the claims in the existing patent, the test under either the "same invention" or "obviousness" branch of the doctrine of double-patenting would have been met.

As mentioned above, double-patenting only arises when considering patents belonging to the same inventor or applicant as the application being examined.

The meaning of "same applicant" for the purpose of double-patenting is based on the definition of *applicant* from section 2 of the *Patent Act*, and therefore includes *an inventor and the legal representatives of an applicant or inventor*. The term *legal representative* itself *includes heirs, executors, administrators of the estate, liquidators of the succession, guardians, curators, tutors, transferees and all other persons claiming through applicants for patents and patentees of inventions or through holders of certificates of supplementary protection*.

In many cases the named inventor(s) and the applicant may be the same, but this is not a requirement. Applicants may have many individuals working on different aspects of related projects and may consequently list different inventors on an application. Regardless of the persons listed as inventors, double-patenting restrictions apply to an applicant as though the same inventors were listed.

The Office takes the position that the doctrine of double-patenting applies if the application being examined belonged to the "same applicant" at any time.

15.06.01 Overlap

Overlap is a term of convenience describing the situation in which an operating embodiment in a claim of an application being examined is identical to an operating embodiment in a claim in an existing patent. The embodiment in the existing patent, being the same as that in the application being examined, therefore acts as a bar against the latter; granting that embodiment in two patents would result in double-patenting.

An operating embodiment can be either the entirety of the claimed subject-matter, or one of several alternatives within a claim. In the latter case, it is possible that the overlap between the claims involves only a small fraction of the scope of the claim in one or both documents. Nevertheless, having the embodiment in question be granted in two patents would result in double-patenting.

Overlap may occur in situations where the claims in the application and the existing patent otherwise appear to be directed to distinct inventions. Where overlap is identified between claims in an application and an existing patent, the claim being examined is not patentably distinct from the claim in the existing patent insofar as the overlapping subject-matter is concerned. The claim being examined is consequently defective due to double-patenting. Removing the overlap, such as by deleting the duplicated subject-matter from the application would remove the double-patenting defect.

Example:

An applicant files two applications consecutively (or concurrently as the case may be). One application claiming feature A issues to patent before the other application. The remaining application claims feature B. Each document has a dependent claim that defines A+B. Granting the application would result in double-patenting for the embodiment A+B, but if the dependent claim directed to that embodiment is removed from the application, and presuming B is not obvious in view of A, the double-patenting defect would be removed.

15.06.02 Existing patent

Double-patenting is often described as barring a second patent in view of an 'earlier patent', and the "sin of double patenting"[91] is often described in terms of the problem of evergreening[92] a monopoly by extending the rights in time through the filing of subsequent applications differing only in uninventive details.

It has been noted, however, that a further patent can provide additional rights to the patentee beyond an extension of the term of the monopoly, and that the overriding principle is the need for a further patent to exhibit novelty and ingenuity in order to be justified.[93] The Office takes the position that having more than one patent to a single invention is not permitted by the doctrine of double-patenting, whether or not the further patent extends the term of the monopoly right granted in the existing patent. The Office takes the position that an "earlier patent" is simply a patent that has already issued and which claims an invention that is not patentably distinct from that in the claims of the application being examined.

This position considers a further patent to be an inappropriate extension of rights both in the sense that the rights in the existing patent would not be exclusive to the existing patent (as provided by section 42 of the *Patent Act*) and that those rights would not be limited to the term of the existing patent (as provided by section 44 of the *Patent Act*).

It is not necessary for the existing patent to have issued from an application having an earlier filing or claim date than the application being examined. There are many reasons for which a later filed application could be issued to patent before an earlier filed application, including many factors controlled by the applicant (the request for examination date, a request for advanced examination, the time taken to respond to reports, etc.).

The Office takes the position that an extension of rights can occur whether or not the rights conferred by an existing patent are still available to the patentee. The expiry of the existing patent does not alter that the issuance of the existing patent bars the grant of a further patent defining an invention not patentably distinct from that in the existing patent. In such cases, the grant of a further patent would restore rights that had expired or been surrendered, thus extending the patent rights.

15.06.03 Co-pending applications

Where two *applications* belonging to the same applicant define inventions that are not patentably distinct from one another, the examiner will inform the applicant that a potential double-patenting issue exists. Preferably, this is done in reports on both applications (where a report is warranted; see below), in order to ensure the applicant is fully aware of the potential problem. This potential defect is not identified in a requisition under section 30 of the *Patent Rules*, since it is not an actual defect until one of the applications issues to patent. Rather, the applicant is advised of the potential defect. Where an application is otherwise in condition for allowance, it will not be held back solely because of a potential double-patenting issue (i.e., a theoretical future defect does not delay allowance of an application). This applies to applications that are in a condition for allowance when first examined; applicants should consequently exercise care when filing applications with closely-related claims, to ensure that all the claims to a given invention are included in a single application. Once a first application issues, the subsequent application(s) will contain an identifiable defect.

Double-patenting is identified between an application and an issued patent regardless of whether the potential defect was identified between the applications while co-pending. This is so whether the double-patenting existed at the time the existing patent's application was allowed, or was subsequently introduced to the application being examined by way of amendment. It is up to the applicant to ensure that all the claims to a given invention are included in a single application. Where a patent issues, but claims to certain aspects of the defined invention were omitted during the application stage (whether accidentally or by design), double-patenting will prevent the granting of those claims in a subsequent patent unless they represent "further invention" over the claims in the existing patent.

15.06.04 Division at the direction of the Office

The Supreme Court has noted that if "patents are granted on divisional applications directed by the Patent Office, none of them should be deemed invalid, or open to attack, by reason only of the grant of the original patent".[94]

Where an examiner has identified a lack of unity of invention in a report on an application, and the applicant files a divisional application in response to that report, the claims in the divisional application are exempt from examination for double-patenting if they are identical to claims identified by the examiner in the parent application as lacking unity and they differ from those retained in the parent application.

Chapter 14 of this manual details the procedures for identifying a lack of unity among the claims of an application. Subsequent to any divisional applications that result from an examiner's identification of multiple inventions in a parent application, a double-patenting defect will not be identified where the claims in the divisional application correspond to claims identified in the report as belonging to a different invention than that defined in the claims retained in the parent. This is typically the case where the applicant has adhered to the claim groupings identified by the examiner.

Where, however, the claims in the divisional do not correspond to the groupings identified in the report on the parent application, whether at filing or as the result of subsequent amendment, they will be examined for double-patenting. This is typically the case where the applicant either determines that groupings different from those identified by the examiner are appropriate, or where subsequent to division the applicant amends the claims (in either the parent or the divisional application) so as to change the claimed invention.

15.07 Selections – June 2016

A *selection*, as the term is used in patent law, rests on the idea that if a disclosure has provided a general description of an invention (e.g. a genus), it may be that certain things falling within the scope of the general teachings can nevertheless be considered to be different inventions (e.g. a species of the genus). These further inventions must be based on the disclosure of substantial advantages not disclosed by the inventors of the broad invention.

The three conditions that must be satisfied for a patentable selection are that:

(i) the *selection* be based on some substantial advantage;
(ii) the whole of the *selection* must possess the advantage; and
(iii) the advantage must be in respect of a quality of a special character peculiar to the whole *selection*.[95]

It is important to note that the advantage (which can include avoiding a substantial disadvantage) must be in comparison to the overall group from which the selection has been made, and be made on the basis of sufficient representative testing and not simply be a comparison to a few isolated members of the overall group.[96]

It should be remembered that in assessing whether an alleged selection is patentable, the patentability of a claim must also be assessed against the usual requirements (novelty, utility, ingenuity, sufficiency of disclosure, etc.)[97]

A newly discovered, substantial advantage is necessary to provide the utility and inventive step to the *selection* for patentability to be acknowledged.[98] Although there is no special or higher disclosure burden for a selection in comparison with any other type of invention, the advantage must be properly disclosed for there to be an invention[99] and, if unclear, the new utility arising from the advantage must also be disclosed. If there is no way to assess the purported "advantage", there is no way for the person skilled in the art to appreciate that an invention has been "correctly and fully" described. An inventor "has in truth disclosed no invention whatever if he merely says that the selected group possesses the advantages. Apart altogether from the question of what is called sufficiency, he must disclose an invention; he fails to do this in the case of a selection for special characteristics, if he does not adequately define them."[100]

A purported selection whose utility has not been established, by demonstration or sound prediction [see Chapter 12 of this manual], is necessarily not an invention. Establishing that there is, in fact, an advantage requires that some point of reference be disclosed. Mere statements that a certain embodiment of an identified group is "preferred" or possesses an otherwise unspecified advantage, benefit or improved property are not sufficient to adequately disclose the substantial advantage necessary to establish inventive selection. [101]

The ingenuity of the alleged *selection* involves a consideration of whether "a particular member or group within [the earlier disclosed] class [has] the same or different properties, and, if different, how different?".[102] Its novelty rests on the fact that the selected aspects of the prior disclosure had not previously been made: per Maughan J. in *I.G. Farbenindustrie*, "[i]t must be remembered, of course, that the selected compounds have not been made before, or the patent would fail for want of novelty".[103]

If an operating embodiment within the *selection* claim has already been made, the advantages of the invention have already been made available and the claimed invention is anticipated. If something within the *selection* claim was merely listed in the prior document, however, without disclosing the advantage upon which the *selection* is based, the requirement for prior disclosure is not met and there is no anticipation.

Where a purported *selection* is not anticipated, it may nevertheless be found to be obvious. The assessment of the obviousness of a *selection* may in some cases be directly assessed by a consideration of whether the alleged advantage is truly unexpected, but may also arise (particularly in the chemical arts) in the context of an *obvious to try* analysis[104] [see 15.02.03].

> *Example:*
>
> An application discloses that it is known to raise sunken ships by pumping a plurality of buoyant bodies through a tube into the ship, and that in the past this had been done by pumping hollow spheres into the ship. The application discloses the use, in particular, of tetrahedral bodies, whose greater packing density increases the effectiveness of the method.
>
> A search of the prior art reveals the use of buoyant bodies to raise sunken ships, but does not indicate the particulars of the shape of said bodies. One piece of prior art appears to illustrate spherical bodies for this purpose.

Claim 1:

A method for raising a sunken ship, the method comprising the steps of: 1) establishing a conduit between a surface pump and the sunken ship, 2) pumping a plurality of generally tetrahedral-shaped buoyant bodies into the ship via the conduit.

Analysis: The prior art teaches the use of buoyant bodies in general, but it appears that only spherical shapes were specifically used. The application teaches that tetrahedral bodies have a substantially higher packing factor than spherical bodies and achieve better packing efficiencies than those of rectilinear or curvilinear bodies. The result of using tetrahedral bodies enables greater packing into a sunken ship and thus higher maximum buoyancy as well as substantially greater retention of the buoyant bodies in the ship (i.e., loss prevention). Given the disclosure of an advantage specific to the use of tetrahedral bodies, it appears their use could be approached as a potential *selection* from among the generic means “buoyant bodies”. Since no prior disclosure of the use of tetrahedra exists, novelty can be acknowledged. The obviousness of claim 1 would have to be evaluated to determine whether the selection of tetrahedra in particular from “buoyant bodies” in general leads to an unexpected benefit such that an inventive step could be acknowledged.

15.08 Provisos – June 2016

Where an applicant is aware of relevant prior art at the time of filing, or becomes aware of relevant prior art during prosecution, they may choose to amend their claim in order to exclude certain embodiments disclosed in the prior art.

One method for excluding known subject-matter is by a *proviso*; a statement that provides that the claim does not include some specified matter. The term *proviso* is used herein to refer to any such exclusionary limitation, regardless of the precise language used to express it (e.g. an attachment means, provided said attachment means is not a rubber-based adhesive; a straight chain alkyl group other than an ethyl or propyl group; a non-field effect transistor).

A *proviso* based on a prior art disclosure may be introduced to an application in order to establish novelty. To comply with subsection 38.2(2) of the *Patent Act* the *proviso* should not introduce new matter (e.g. by broadening the claim outside what was reasonably inferable from the original specification).

A *proviso* may be used to establish novelty, or inventive step over the prior art. When introduced as an amendment, a *proviso* that excludes a feature that was not necessarily present in the original claim should be very carefully considered, since the newly-identified feature is presumably not required for the proper operation of the claimed subject-matter.

In general, a *proviso* will therefore render a claim patentable where the broad claim would have been considered novel and inventive if it were not for an isolated earlier disclosure of something within the claim. A broad product claim might, for example, be anticipated by a specific product suitable for the same purpose as that taught by the applicant, but which was disclosed in the earlier document for a different use. Excluding the specific product might render the remaining subject-matter of the claim novel. Depending on the relationship between the two uses, the *proviso* might be sufficient to also render the amended claim unobvious.

Where a claim is amended to include a number of *provisos* to establish novelty and inventiveness, a greater level of scrutiny is necessary to ensure that the remaining subject-matter is still a single invention, and that the nature of the invention described in the original application has not been obscured or changed (e.g. by defining the invention solely in terms of what it is not, rather than what it is).

> Example:
>
> An application describes the therapeutic effectiveness of a class of compounds which have, in common, structural element A. Prior art application D1 discloses compound X as a useful drug in the therapy of disease Y, X comprises structural element A. Subsequent to the publication of D1, the applicant found that A is an element essential to the effective treatment of disease Y in the class of compounds.
>
> Claims:
>
> 1. A compound having <structural element A> for use in treating disease Y.
>
> 2. A compound having <structural element A> for use in treating disease Y, provided said compound is not compound X.
>
> Analysis: Claim 1 is anticipated by D1 because compound X has established utility as an effective treatment for Y and comprises structural element A.
>
> Claim 2 is not anticipated by D1 as the proviso removes the applicability of D1 by tying the effective treatment to previously unknown importance of element A in said treatment.
>
> Having been deemed novel in view of the proviso, the inventive concept of claim 2 would require additional analysis to determine inventiveness in view of the common general knowledge at the claim date.

Information regarding unity and provisos can be found in subsection 14.08.07 of this manual.

Endnotes for Chapter 15

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[1]. *Shire Biochem Inc. v. Minister of Health* 2008 FC 538 at paragraph 61 ; *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153, 2002 SCC 77 at paragraph 37

[2]. *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.* 2008 SCC 61 at paragraphs 24-27 and 33-37

[3]. *Eli Lilly and Company v. Apotex Inc.* 2009 FC 991 at paragraph 397*; Shire Biochem* (supra at 1) at paragraph 75.

[4]. *Apotex v. Sanofi-Synthelabo* (supra at 2) at paragraph 25

[5]. *Apotex v. Sanofi-Synthelabo* (supra at 2) at paragraphs 33-37

[6]. *Apotex v. Sanofi-Synthelabo* (supra at 2) at paragraphs 24-46; *Lundbeck Canada Inc. v. Ratiopharm Inc.* 2009 FC 1102 at paragraph 69; *Abbott Laboratories v. Minister of Health* 2008 FC 1359 [*Abbott/Sandoz*] at paragraph 59 (aff'd 2009 FCA 94).

[7]. *Bristol-Myers Squibb Canada Co. v. Apotex Inc.* 2009 FC 137 at paragraph 35

[8]. *Apotex v. Sanofi-Synthelabo* (supra at 2) at paragraph 25, citing *Synthon B.V. v. SmithKline Beecham plc* 2005 UKHL 59 at paragraph 32

[9]. *Schmuel Hershkovitz v. Tyco Safety Products Canada Ltd.* 2009 FC 256 at paragraph 100; *Shire Biochem* (supra at 1) at paragraph 65

[10]. *Abbott/Sandoz* (supra at 6) at paragraphs 59 and 60; *Johnson & Johnson Inc. v. Boston Scientific Ltd.* 2008 FC 552 at paragraph 309; this principle is also inherent in wording of subsection 28.2(*1*) of the *Patent Act*.

[11]. *Abbott/Sandoz* (supra at 6) at paragraph 75 (aff'd 2009 FCA 94)

[12]. *Steel Co. of Canada Ltd. v. Sivaco Wire and Nail Co.* [(1973), 11 C.P.R. (2nd), 153 (F.C.T.D.)] at page 190, citing *General Tire & Rubber Co. v. Firestone Tyre & Rubber Co. Ltd.* [1972] R.P.C. 464 at page 486; *Abbott Laboratories v. Canada (Minister of Health)* 2006 FCA 187 [*Abbott/Ratiopharm*] at paragraph 24, citing *Smithkline Beecham PLC's (Paroxetine Methanesulfonate) Patent*, [2005] UKHL 59 at paragraph 22, itself citing *Merrell Dow Pharmaceuticals Inc v N.H. Norton & Co. Ltd.* [1996] R.P.C. 76 at page 90

[13]. *Apotex v. Sanofi-Synthelabo* (supra at 2) at paragraph 27

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[14] Free World Trust v. Électro Santé Inc. 2000 SCC 66 at paragraph 26 citing Consolboard Inc. c. MacMillan Bloedel (Saskatchewan) Ltd. [1981] 1 RCS 504 [(1981), 56 CPR (2nd), 145 (CSC)] per Dickson J. at p. 534

[15] See, e.g., *Hershkovitz v. Tyco* (supra at 9) at paragraph 105

[16] *Reeves Bros. v. Toronto Quilting* [(1978), 43 C.P.R. (2nd), 145 (F.C.T.D.)] at page 157, apparently relying on a proposition stated at least as early as *Hill v. Evans* (1869), 4 DeG. F. & J. 988, 45 E.R. 1195 at page 301. The continued relevance of the factors enumerated in *Reeves Bros.* was discussed in *Johnson & Johnson* (supra at 10) at paragraph 295.

[17] *Lovell Manufacturing Co. v. Beatty Bros. Ltd.* [(1962), 41 C.P.R. (1st), 18 (Ex. Ct.)] at page 45, citing *Hill v. Evans* (supra at 1621) at page 300

[18] *Abbott/Ratiopharm* (supra at 12) at paragraphs 24 and 25; *Eli Lilly v. Apotex* (supra at 3) at paragraph 397; *AstraZeneca Canada Inc. v. Apotex Inc.* 2010 FC 714 at paragraph 124

[19] *Lightning Fastener Co. v. Colonial Fastener Co*. [1933] S.C.R. 377 (affirming [1932] Ex. C.R. 101) at page 381.

[20] *Shire Biochem* (supra at 1) at paragraph 63

[21] *Baker Petrolite Corp v Canwell Enviro Industries Ltd* 2002 FCA 158 at para. 42

[22] *Baker Petrolite* (supra at 21) paragraphs 35 and 42

[23] *Bauer Hockey Corp. v. Easton Sports Canada Inc.* 2010 FC 361 at paragraphs 216-220

[24] *Baker Petrolite* (supra at 21) para 42 citing *Merrell Dow Pharmaceuticals Inc. v. H.N. Norton & Co. Ltd.* (1995), [1996] R.P.C. 76 (H.L.) at p. 86

[25] *Bauer* (supra at 23) citing *Lux Traffic Controls Limited v. Pike Signals Limited*, [1993] R.P.C. 107 (Pat. Ct.) at p.132

[26] *Wenzel Downhole Tools Ltd. v. National-Oilwell Canada Ltd* 2012 FCA 333 at paragraphs 68 and 74

[27] *Baker Petrolite* (supra at 21) at paragraph 42

[28] *Baker Petrolite* (supra at 21) at paragraph 42; *Gibney v. Ford Motor Co. of Canada* [(1967), 35 Fox Pat. C. 143] at paragraph 61

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[29] *Abbott/Ratiopharm* (supra at 12) at paragraphs 23 to 25; *Calgon Carbon Corporation v. North Bay (City) 2006 FC 1373* at paragraphs 114 to 136

[30] See *Metalliflex Limited v. Rodi & Wienenberger Aktiengesellschaft, [1961] S.C.R. 117*

[31] Abbott/Sandoz (supra at 6) at paragraphs 69-73; *Lundbeck* (supra at 6) at paragraphs 20, 118 and 136;

[32] *Astrazeneca AB v. Apotex Inc. 2007 FC 688* at paragraphs 50-53

[33] *The King v. American Optical Co.* [(1950), 13 C.P.R. (1st), 87 (Ex. Ct.)] at pages 109-110, citing *Clay v. Allcock & Co.* (1906), 23 R.P.C. 745 at page 750

[34] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.* [(1981), 56 C.P.R. (2nd), 145 (S.C.C.)] at page 161, citing *American Optical* (supra at 33) at pages 109-110

[35] *Commissioner of Patents v. Farbewerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning* [1964] S.C.R. 49, [(1963), 41 C.P.R. (1st), 9 (S.C.C.)] at page 17

[36] The requirement codified in section 28.3 of the *Patent Act* that an invention not be obvious in view of certain prior art implies a requirement for ingenuity - see *Janssen-Ortho Inc. v. Novopharm Ltd. 2006 FC 1234* at paragraphs 109-110; Canamould Extrusions Ltd. v. Driangle Inc. 2003 FCT 244 at paragraph 61 (rev'd on other grounds); *Baker Petrolite Corp. v. Canwell Enviro Industries Ltd. 2001 FCT 889* at paragraphs 94-96 (rev'd on other grounds); *Harvard College v. Canada (Commissioner of Patents)* [(2000), 7 C.P.R. (4th), 1 (F.C.A.)] at paragraph 105 (rev'd on other grounds); *Diversified Products v. Tye-Sil* [(1991), 35 C.P.R. (3rd), 350 (F.C.A.)] at page 366.

[37] *Janssen-Ortho* (supra at 36) at paragraphs 99, aff'd 2007 FCA 217. *Baker Petrolite* (supra at 21).

[38] Janssen-Ortho Inc v Novopharm Ltd, 2004 FC1631 para. 37.

[39] The requirement codified in section 28.3 of the *Patent Act* that an invention not be obvious in view of certain prior art implies a requirement for ingenuity - see Janssen-Ortho (supra at 36) at paragraphs 109-110; Canamould Extrusions (supra at 36) at paragraph 61 (rev'd on other grounds); Baker Petrolite (supra at 21) at paragraphs 94-96 (rev'd on other grounds); Harvard College (supra at 36) at paragraph 105 (rev'd on other grounds); *Diversified Products v. Tye-Sil* [(1991), 35 C.P.R. (3rd), 350 (F.C.A.)] at page 366.

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[40] *Beloit Canada Ltd. v. Valmet Oy* [(1986), 8 C.P.R. (3rd), 289 (F.C.A.)] at page 293

[41] *Diversified Products* (supra at 36) at page 366

[42] *Xerox of Canada Ltd. v. IBM Canada Ltd.* [(1977), 33 C.P.R. (2nd), 24 (F.C.T.D.)] at page 52, citing *Samuel Parkes & Co. Ltd. v. Cocker Bros. Ltd.* [(1929), 46 R.P.C. 241] at page 248.

[43] *The King v. Uhlemann Optical Co.* [(1951), 15 C.P.R. (1st), 99 (S.C.C.)] at pages 104-105; *Wandscheer v. Sicard Ltd* [1948] S.C.R. 1 [(1947), 8 C.P.R. (1st), 35 (S.C.C.)] at page 48; both cases citing *Samuel Parkes* (supra at 42) at page 248.

[44] *Apotex v. Sanofi-Synthelabo* (supra at 2) at paragraphs 61-64; *Janssen-Ortho Inc. v. Novopharm Limited* 2007 FCA 217 at paragraph 25.

[45] *Apotex v. Sanofi-Synthelabo* (supra at 2) at paragraph 67. The approach is based on that taken in *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.* [1985] R.P.C. 59 (C.A.) and refined in *Pozzoli SPA v. BDMO SA* [2007] EWCA Civ 588 and may be termed the Windsurfing/Pozzoli approach.

[46] *Merck & Co., Inc. v. Pharmascience Inc.* 2010 FC 510 at paragraphs 32 and 35

[47] *Bayer Aktiengesellschaft v. Apotex Inc.* [(1995), 60 C.P.R. (3rd), 58 (On.Ct.G.D.); [*Bayer AG*] at page 79; *Johnson & Johnson* (supra at 10) at paragraph 97; *Lundbeck Canada Inc v. Minister of Health* 2009 FC 146 at paragraph 36; *Bauer* (supra at 23) at paragraph 122

[48] From *Beloit* (supra at 40) at page 294 we know them to be a paragon of deduction. See also the comments on point in *Janssen-Ortho* (supra at 36) at paragraph 113.

[49] *Bayer AG* (supra at 47) at page 79; *Merck-Frosst - Schering Pharma GP v. Teva Canada Limited* 2010 FC 933 at paragraphs 68 and 69

[50] *Servier Canada Inc. v. Apotex Inc.* 2008 FC 825 at paragraph 99; *Lundbeck* (supra at 6) at paragraph 29; *Sanofi-Aventis Canada Inc. v. Apotex* 2009 FC 676 at paragraph 80

[51] *Almecon Industries Ltd. v. Nutron Manufacturing Ltd.* (1997) 72 C.P.R. 3d 397 at page 401.

[52] *Whirlpool Corp. v. Camco Inc.* 2000 SCC 67 at paragraph 74*; Servier* (supra at 50) at paragraph 254; Newco Tank Corp v. Canada (Attorney General) 2014 FC 287 at paragraph 28.

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[53] *Axcan Pharma Inc. v. Pharmascience Inc.* 2006 FC 527 at paragraph 38

[54] *Servier* (supra at 50) at paragraph 236

[55] *Free World Trust* (supra at 14) at paragraph 44, quoting H.G. Fox from his *Canadian Law and Practice Relating to Letters Patent for Inventions* [(1969), 4th Ed.] at page 184; *Whirlpool* (supra at 52) at paragraph 49, citing *Lister v. Norton Brothers and Co.* [(1886), 3 R.P.C. 199 (Ch.D.)] at page 203

[56] *Free World Trust* (supra at 14) at paragraph 44

[57] *Servier* (supra at 50) at paragraph 254

[58] *Ratiopharm Inc. v. Pfizer Limited* 2009 FC 711, at paragraph 30, *aff'd* 2010 FCA 204

[59] *GlaxoSmithKline Inc. v. Pharmascience Inc.* 2008 FC 593 at paragraph 35

[60] *Janssen-Ortho* (supra at 36) at paragraph 90.

[61] *Bauer* (supra at 23) at paragraph 121

[62] *Merck v. Pharmascience* (supra at 46) at paragraph 40; *AstraZeneca* (supra at 18) at paragraph 39

[63] *Apotex v. Sanofi-Synthelabo* (supra at 2) at paragraph 37

[64] *Sanofi-Aventis Canada Inc. v. Apotex* 2009 FC 676 at paragraph 304

[65] *Whirlpool* (supra at 52) at paragraph 74

[66] *Eli Lilly v. Apotex* (supra at 3) at paragraph 97, citing *General Tire & Rubber Co. v. Firestone Tyre & Rubber Co. Ltd*, [1972] RPC 457 at pages 482-483

[67] *Eli Lilly v. Apotex* (supra at 3) at paragraph 421

[68] *Shire Biochem* (supra at 1) at paragraph 25; *Eli Lilly Canada Inc. v. Novopharm Ltd.* 2007 FC 596 at paragraph 142; *Pfizer Canada Inc. v. Novopharm Ltd.* 2005 FC 1299 at paragraph 78; *Whirlpool Corp. v. Camco Inc.* [(1997), 76 C.P.R. (3rd), 150 (F.C.T.D.)] at page 186

[69] Allergan Inc v Canada (Health) and Cobalt Pharmaceuticals, 2014 FC 566 at paragraph 25; Allergan Inc v Canada (Health) and Apotex Inc, 2014 FC 567 at paragraph 25

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[70]. *Janssen-Ortho* (supra at 36) at paragraph 113, aff'd 2007 FCA 217 at paragraph 25; these factors are considered to remain relevant in view of the guidance of the Supreme Court in *Apotex v. Sanofi-Synthelabo* (supra at 2).

[71]. *Canadian Gypsum Co. v. Gypsum, Lime & Alabastine, Canada Ltd.* [1931] Ex. C.R. 180 at paragraph 12

[72]. *Sanofi-Aventis Canada Inc. v. Ratiopharm Inc. 2010 FC 230* [*Ratiopharm*] at paragraphs 83-87; Commissioner's Decsion1304 at paragraph 43

[73]. *Apotex v. Sanofi-Synthelabo* (supra at 2) at paragraph 68

[74]. *Wenzel Downhole Tools Ltd. v. National-Oilwell Canada Ltd.*, 2011 FC 1323 at paragraphs 193 to 197 where the *obvious-to-try* test was applied to downhole drilling equipment. Comments on the appropriateness of the test were made on appeal (see 2012 FCA 333) at paragraphs 91 to 108, especially paragraph 95.

[75]. Apotex v. Sanofi-Synthelabo (supra at 2) at paragraph 59-69, especially at 59, 64, 68 and 69; *Sanofi-Aventis v. Apotex Inc.,* 2013 FCA 186 at paragraphs 74-80

[76]. *Apotex v. Sanofi-Synthelabo* (supra at 2) at paragraph 68

[77]. *The King v American Optical Co.* (supra at 33) at page 98

[78]. Shmuel Hershkovitz (supra at 9) at paragraph 148 referring to R.H. Barrigar, *Canadian Patent Act Annotated*, 2nd ed. (Aurora: Canada Law Book, 2008) at PA-28.11-12; *Domtar Ltd. v. McMillan Bloedel Packaging Ltd.* (1977), 33 C.P.R. (2d) 182 at 189-91 (F.C.T.D.), affirmed (1978), 41 C.P.R. (2d) 182 (F.C.A.).

[79]. *Crila Plastic Industries Ltd. v. Ninety-eight Plastic Trim Ltd.* 18 C.P.R. (3d) 1 at pages 1 and 7 to 9, affirming 10 C.P.R. (3d) 226, referring to *Domtar* (supra at 78).

[80]. *Visirecord of Canada Ltd. v. Malton* [1958] Ex. C.R. 116 at paragraph 59, citing *Lightning Fastener Company Limited v. Colonial Fastener Company, Limited* [1932] Ex. C.R. 101 at page 106

[81]. *Visirecord* (supra at 80) at paragraph 60, citing *Lowe-Martin Company Ltd. v. Office Specialty Manufacturing Company Ltd.* [1930] Ex. C.R. 181 at page 187

[82]. *Johnson Controls, Inc. v. Varta Batteries Ltd.* [(1984), 80 C.P.R. (2nd), 1 (F.C.A.)] at pages 12-13

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[83]. *Visirecord* (supra at 80) at paragraph 61, citing *The Railroad Supply Co. v. The Elyria Iron and Steel Co.* [1917] Patent Office Gaz. (U.S.) vol. 239, at page 658

[84]. *Visirecord* (supra at 80) at paragraph 62, citing *Helson v. Dominion Dustless Sweepers Co. Limited* (1923), 23 O.W.N. 597 at page 598

[85]. *Genpharm Inc. v. Procter & Gamble Pharmaceuticals Canada, Inc.* 2004 FCA 393 at paragraph 47

[86]. *Uview Ultraviolet Systems Inc. v. Brasscorp Ltd.* 2009 FC 58 at paragraph 224.

[87]. *Consolboard* (supra at 34) at page 168

[88]. *Whirlpool* (supra at 52) at paragraph 63-67

[89]. *Abbott Laboratories v. The Minister of Health* 2009 FC 648 at paragraph 187, referring to *Consolboard* (supra at 34) at page 169, itself referring to *Farbwerke Hoechst* (supra at 35) at page 13

[90]. *Farbwerke Hoechst* (supra at 35) at page 13.

[91]. *GlaxoSmithKline Inc. v. Apotex Inc.* 2003 FCT 687 at paragraphs 89-91

[92]. *GlaxoSmithKline* (supra at 91) at paragraph 37.

[93]. *GlaxoSmithKline* (supra at 91) at paragraphs 87-91; *Bayer Inc. v. Canada (Minister of National Health and Welfare*) 154 F.T.R [(1998), 82 C.P.R. (3rd), 359 (F.C.T.D.), aff'd (2000), 6 C.P.R. (4th), 285 (F.C.A.] at paragraph 33. See also Apotex Inc. v. Merck & Co. 2006 FCA 323 at paragraph 49.

[94]. *Consolboard* (supra at 34) at page 169

[95]. *I.G. Farbenindustrie A.G.'s Patents* [(1930), 47 R.P.C. 289] at pages 322-323; these criteria appear to have been endorsed in Canada at least as early as 1947 in *Minerals Separation North American Corp. v. Noranda Mines, Ltd.* [(1947), 12 C.P.R. (1st), 102 (Ex.Ct.)] at pages 163-164) and were endorsed by the Supreme Court in *Apotex v. Sanofi-Synthelabo* (supra at 2) at paragraph 10.

[96]. *GlaxoSmithKline Inc. v. Pharmascience Inc.* 2008 FC 593 at paragraph 70 and at paragraph 51 with reference to *Dreyfus and Others Application* [(1945), 62 R.P.C. 125 (H.L.)] at page 133; *I.G. Farbenindustrie* (supra at 95) at page 327

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[97] Eli Lilly Canada Inc. v. Novopharm Limited 2010 FCA 197 at paragraphs 27, 30; *Ratiopharm* (supra at 58) at paragraph 175, aff'd 2010 FCA 204 at paragraph 33

[98] *Pfizer Canada Inc. v. Canada* 2006 FCA 214 at paragraph 4

[99] Pfizer Canada Inc. v. Ranbaxy Laboratories Limited 2008 FCA 108 at paragraph 59; Eli Lilly Canada Inc. v. Apotex Inc. 2007 FC 455 at paragraph 89

[100] *I.G. Farbenindustrie* (supra at 95) at page 323

[101] see, e.g., *Eli Lilly Canada Inc. v. Novopharm Limited* 2009 FC 235 at paragraph 100; *Eli Lilly Canada Inc. v. Novopharm Ltd.* (supra at 68) at paragraph 162; *Ratiopharm* (supra at 58) at paragraph 179;

[102] *Ratiopharm* (supra at 58) at paragraph 175, aff'd 2010 FCA 204 at paragraphs 27-28

[103] *Apotex v. Sanofi-Synthelabo* (supra at 2) at paragraph 9; *I.G. Farbenindustrie* (supra at 95) at page 321

[104] *Pfizer Limited v. Ratiopharm Inc.* 2010 FCA 204 at paragraphs 27-28

Chapter 16
Computer-Implemented Inventions

16.01 Scope of this chapter

The purpose of this chapter is to highlight Office practice as it pertains in particular to computer-implemented inventions.

The term “computer” is used in this chapter to refer to an electronic device comprising a processor, such as a general-purpose central processing unit (CPU), a specific purpose processor or a microcontroller. A computer is capable of receiving data (an input), of performing a sequence of predetermined operations thereupon, and of producing thereby a result in the form of information or signals (an output).

Depending on context, the term “computer” will mean either a processor in particular or can refer more generally to a processor in association with an assemblage of interrelated elements contained within a single case or housing.

Guidance provided herein in respect of “computers” may apply, where the term has been used to refer to a device comprising a processor, to devices such as network servers, personal digital assistants (PDA), multi-function cell phones, and the like, or even to processor-containing televisions, music or video playback devices and appliances such as bread makers or coffee machines.

In certain contexts, the term “computer” may be used to encompass a device interacting with certain ubiquitous peripherals, such as a keyboard, mouse or display, necessary for interacting with the computer itself. In this sense, the term “computer” may refer to a “general purpose computer” such as a desktop or laptop computer capable of receiving input, such as via a keyboard, and providing output, such as to a display means.

Where references are made to software “stored on” a physical memory, these are intended to simply refer to the fact that the physical memory is storing the software. No distinction is made herein between memory types which are best described as having software “stored in” the memory and those that are best described as having the software “stored on” the memory.

In reading this chapter, it should be borne in mind that its purpose is to clarify, through elaboration, the application of the more generic teachings of other chapters to the particular issues encountered with computer-implemented inventions.

Nothing in this chapter should be interpreted as providing exceptions to any practice of general applicability set out in any other chapter. Throughout this chapter, reference is made to the nature of the contribution in a claimed invention. Additional guidance on the contribution approach used to assess whether a patentable contribution has been made can be found in Chapter 13 of this manual.

16.02 Subject-matter

As with any invention, in order to be patentable under the *Patent Act* the claimed subject-matter of a computer-implemented invention must fall within one of the five categories found within the section 2 definition of "invention", namely art, process, machine, manufacture or composition of matter.

The following sections set out how the five categories of invention apply to computer-implemented inventions in particular, and consequently refine the more general guidance provided in Chapter 12 of this manual.

A computer-implemented invention may be claimed as a method (art, process or method of manufacture), machine (generally, a device that relies on a computer for its operation), or product (an article of manufacture). Certain subject-matter relevant in the computer arts may not be claimed as such, including computer programs [16.08.04], data structures [16.09.02], and computer-generated signals [16.09.05].[1]

A guiding principle in respect of computer-related inventions was provided by the Federal Court of Appeal in *Schlumberger*, which noted that "the fact that a computer is or should be used to implement a discovery does not change the nature of that discovery", and also that the presence of a computer cannot effect the "transforming into patentable subject-matter [of] what would, otherwise, be clearly not patentable".[2]

16.02.01 Art

Computer-implemented inventions falling within the category *art* are typically claimed as methods.

Many methods involve the use of a computer or an apparatus or device including a computer. A method that, on its own merits, would be considered non-statutory does not become statutory simply by virtue of some part of the method being carried out on or by a computer. The method itself, as a whole, must be a solution to a practical problem and must lie within a field of technology.

Claims to computer-implemented methods for playing games or creating works of art do not define inventions that belong to a field of technology and do not come within the definition of invention in section 2 of the *Patent Act* [see sections 12.06.05 (Games) and 12.06.03 (Fine arts) of this manual].

A method of controlling a computer's operations so as to achieve a technological result,[3] in contrast, would come within the definition of invention in section 2 of the *Patent Act*. In such a method, the electronic processes within the computer are considered to satisfy the requirement that the method include (either explicitly or implicitly) at least one act performed by a physical agent upon a physical object, producing in that object some change of condition.

16.02.02 Process

As noted in section 12.02.02 of this manual, a *process* implies the application of a method to a material or materials. To be statutory, a process must apply a statutory method.

When assessing the contribution of a computer-implemented process, it must be borne in mind that the necessary ingenuity can arise from the method, from the material or materials, or from the recognition that applying the method to the material or materials leads to an unexpected useful result.

16.02.03 Machine

A device such as a computer, or an apparatus or system including a computer associated with other devices, is generally viewed as falling within the category *machine*.

Whether or not a claim to a device defines a patentable invention depends on the presence of a contribution in the claimed matter and the nature of this contribution [see section 13.05.03 of this manual]. As noted in section 13.05.03*b*, for a claim to be patentable it must define at least one statutory element that forms part of the contribution. For a claim to a device to be patentable, the device itself must therefore be a contributed practical form. That is, the device must provide a novel and unobvious technological solution to a technological problem.

Determining whether or not this is the case can be performed by assessing the device itself, but in many cases can also be performed indirectly by reference to the method implemented by the device. Where a statutory method is implemented by a computer, apparatus or system, a device capable of implementing the entire method is necessarily a solution to a practical problem. Presuming the device has been specifically modified to implement the method, such that it is novel and unobvious, it will be a statutory contribution. The patentability of a device is not negated, however, from the mere fact that the device is intended to implement or to be used in a non-statutory method. The question to be addressed in such cases remains whether the device provides a novel and inventive technological solution to a technological problem.

Where a device does provide such a solution, its patentability does not depend on whether it was adapted by providing new hardware or by controlling existing hardware in a particular manner by the addition of software or firmware (software programmed into a read-only memory).

Note that the "technological solution to a technological problem" does not have to be in relation to the operation of the computer as a general purpose device (e.g. it is not necessary that a computer be made more efficient or reliable), but could be simply that the general purpose device has been technologically adapted to act as a special purpose device. Thus, presuming novelty and ingenuity, any of the following provide technological solutions to technological problems and would be viewed as contributed devices: a computer programmed to allow its speakers to simulate "surround sound" (known hardware controlled by new software), a computer adapted to operate using two central processing units (new arrangement of known hardware, controlled by new software), a computer programmed to allocate memory to video processing in a manner that increases the efficiency of the device when running several applications (known hardware controlled by new software), and a computer whose motherboard has an inventive new video card slot with a faster data transfer rate (new hardware).

Where a computer or other device does not provide a solution to a technological problem, the computer or device as a whole is not a contributed practical form of an invention. Where such a device is further defined in terms of discrete non-statutory features, the claim would be objected to on the ground that it does not define a statutory "invention" within the meaning of section 2 of the *Patent Act* [see section 13.05.03*b* of this manual]. For example, a computer or other programmable device cannot be patentably distinguished from other computers simply on the basis of stored information; the stored information does not cause the computer to become a new and unobvious solution to a practical problem [see section 12.06.07 of this manual].

16.02.04 Manufacture

The category *manufacture* encompasses both processes for manufacturing and the products made by such processes [see section 12.02.04 of this manual]. As noted in 16.02.03, a device including a CPU is generally viewed as falling within the category *machine*. The category *manufacture* is therefore considered to apply to computer-implemented inventions either where a computer is used to control a manufacturing process, or where a non-*machine* computer product is claimed. The principles discussed in 16.02.02 apply equally to computer-controlled manufacturing *processes*.

The concept of a non-*machine* computer product applies to a physical memory storing computer-executable instructions. A computer program *per se* is not statutory because it is disembodied. A physical medium storing the program, however, may be considered a *manufacture*. The patentability of such products depends on the nature of the contribution, and is discussed in 16.08.04.

16.02.05 Composition of matter

The category of invention *composition of matter* relates to chemical compounds, compositions and substances and is not of great significance to computer-implemented inventions. A computer-controlled method or process for manufacturing compositions of matter could be evaluated under the category *art* or *process* as the case may be.

16.03 Examining computer claims

A patentable claim must include a statutory contribution. Where a claim is directed to a computer, it must be determined whether the device itself is part of the contribution - that is, whether the computer itself may be considered novel and inventive.

In evaluating whether the computer has been contributed, it is first necessary to identify the essential elements of the device; *i.e.*, those that, as a set, provide a technological solution to a technological problem [see section 13.05.03 of this manual]. For the computer to be patentable, this set of elements must be novel and inventive.

As noted in 16.02.03, where the machine has been specially adapted to implement the entirety of a patentable (statutory, useful, novel and inventive) method, the machine is considered to be a technological solution and is patentable.

Where a machine implements a non-statutory method, in contrast, inventive ingenuity associated with the method *per se* does not provide the inventive step necessary to support the patentability of a machine implementing that method. The inventive ingenuity necessary to make the machine patentable must arise in relation to adapting the machine to implement the method.

16.03.01 Adapting a computer to solve a problem

A computer can be adapted to solve a problem either by its hardware, software or a combination thereof. Where the adaptation is performed via hardware, this will typically permit a structural comparison of the computer to other computers and will facilitate the assessment of novelty and ingenuity.

More often, however, a computer will be adapted via software. In evaluating whether a computer adapted by software is the result of ingenuity, it is useful to draw a distinction between the design of a computer program and the expression of that program in a specific programming language.

Designing a computer program comprises steps such as developing a method to be implemented by the computer and creating flow charts, design diagrams or pseudocode to describe the method steps to be performed by the computer in order to solve a problem. Furthermore, specific operations and their necessary sequence to enable the computer to implement the method are determined.

Once the design is completed, the computer program is expressed as lines of code. Expressing a computer program in a specific programming language, however, is considered to fall within the common general knowledge of an uninventive skilled programmer and is not considered to require inventive effort. This person skilled in the art is considered to be able to express the program in any number of different programming languages without the exercise of judgement or reasoning, and therefore without the exercise of ingenuity. Consequently, the inventive ingenuity necessary to provide patentability to a computer is never found simply in writing computer code to express a developed program.

16.03.02 Patentability and programming

A computer program is not, by itself, statutory subject-matter. However, if the result of running the program on a computer is to provide a novel and inventive technological solution to a technological problem, then the program is viewed as modifying the technological nature of the computer as a whole. The program in such cases is not a discrete element of a claim to the computer.

In considering whether a program will bestow patentability on an otherwise-known computer, the goal is therefore to identify whether it provides a novel and inventive technological solution to a technological problem.

In cases where the computer program expresses a statutory method (*i.e.* a series of steps which provides a technological solution to a technological problem), the program will be considered to be technological in nature. If the method is also both novel and inventive, then the programmed computer would be patentable. Thus, as noted in 16.02.03, where a computer implements the entirety of a patentable method, the computer is patentable. If the method, while technological, is not novel and inventive then it is not sufficient to render the computer patentable. Note that where the computer only implements part of a patentable method, care must be taken to base the assessment only on those parts of the method which take place on the computer, and not on the basis of the method as a whole.

On the other hand, where the computer program expresses a non-statutory method, the non-statutory method itself is not a patentable contribution, regardless of whether it is novel and inventive. The patentability of the computer claims in such cases will depend on additional elements defining how the computer is adapted to implement the method. These additional elements may or may not be novel and inventive, depending on their nature and complexity and the state of the art in programming at the relevant date. Where inventive effort is needed to enable a computer to implement a method in a novel way, a technological solution to a technological problem has been contributed.

In determining whether the program's design is inventive or not, the examiner will be guided by the description. Paragraph 80(1)(*d*) of the *Patent Rules* states that the description shall "describe the invention in terms that allow the understanding of the technical problem, even if not expressly stated as such, and its solution".

Thus, it should be clear from the description what technical (technological) problem is being addressed, and what solution is being proposed by the inventors. Where the examiner is considering whether ingenuity was required in reducing an algorithm to a specific series of operations to be carried out by the computer program, the level of detail included in the description will be informative.

Where the application includes no details regarding how the computer program is to operate, this suggests the applicant considers the manner of implementing their method to be uninventive. It can be appropriately concluded by the examiner that there is no invention in the reduction to practice of the method. This conclusion is not prejudicial to the applicant, since even if the applicant were incorrect in considering the development of the program to be uninventive it would nevertheless follow that the description would not be enabling. Given the lack of disclosure, the programmer would be called upon to exercise inventive effort in determining how the program is to operate.

Where a greater level of detail is provided, the examiner must consider whether the specific implementation is an inventive solution to a technological problem in respect of the operation of the computer, and thereby determine if the computer itself has been contributed.

16.03.03 Examples

The following examples illustrate how the guidance in this chapter can be applied in practice, particularly where the subject-matter of the invention lies outside the field of computers *per se*.

Example 1:

An application discloses the atomic coordinates of protein X and a crystal structure of said protein. A three-dimensional molecular modelling algorithm is applied to the atomic coordinates to determine the spatial coordinates of the binding pocket of protein X and subsequently, *in silico* screening is performed to search for compounds that interact with protein X.

Prior art document D1 discloses:

- molecular modelling software capable of generating a 3D representation of a binding pocket from the atomic coordinates of a protein,
- that the software is capable of performing *in silico* screening to predict whether known molecules will bind with the binding pocket, and
- databases storing the atomic coordinates of various molecules.

Claims:

1. Atomic coordinates of protein X.

2. A computer readable medium comprising the atomic coordinates of claim 1.

3. A computer-implemented method for identifying compounds that interact with protein X, comprising the steps of:
    a. generating on a computer a three-dimensional model of protein X from the atomic coordinates of claim 1;
    b. identifying a binding pocket in the model of protein X;
    c. searching within a database of structurally defined compounds to identify compounds that are structurally complementary to the binding pocket of protein X;
    d. calculating the binding energy for each structurally complementary compound identified in step (c) to the binding pocket of protein X; and
    e. generating an output identifying compounds with binding energies meeting preselected conditions.

Analysis: Claim 1 defines atomic coordinates, which are merely descriptive information relating to the protein. The claim is not, by its form, directed to a statutory invention under section 2 of the *Patent Act*. Claim 2 defines this information when stored on a carrier. It is statutory in its form, but does not include a statutory contribution (the storage medium itself being, self-evidently, known).

Claim 3 defines a method whereby a computer generates a 3D model of a molecule, analyses the model to identify a binding pocket, and attempts to find target molecules whose structures are complementary to the binding pocket and which will bind to the binding pocket. Several of the steps involve computer operations that could potentially be technological innovations in the operation of a computer, including generating the 3D model (step a), analysing the model to identify a binding pocket (step b), and performing the shape-matching and energy minimization calculations (steps c and d). Claim 3 is directed, by its form, to a statutory method. In view of D1, however, these operations are already known and therefore do not form part of the contribution. The specific atomic coordinates of protein X do not modify the technological manner by which the computer performs the calculations, and therefore the model of protein X is a discrete element of the claim. The model of protein X is not itself a statutory invention (could not be a statutory contribution). After having set out a contribution analysis, in view of D1, the claim can be found defective under section 2 of the *Patent Act* on the basis that no contributed statutory subject-matter has been defined and the model of protein X is not a statutory invention.

The analysis of claim 3 would be guided by the description of the application. The level of detail provided in respect of how the computer performs the various modelling, analysis, shape fitting and energy minimization steps would be indicative of whether technological obstacles were overcome by the inventors in respect of these operations. A lack of detail, or for example a reference to the known molecular modelling software of D1, would be a strong indication that there was no innovation in how the computer performed these operations. Note that if specific details were given in respect of how the computer operations were performed, these would need to be claimed in order to distinguish the method from that of D1.

Note that the conclusion with respect to claim 3 is arrived at after having performed a contribution analysis, in view of the substance of the claimed invention. This can be contrasted with the statement made with respect to the claim in example 5 in section 17.02.04 of this manual, which indicates only that, by its form, that claim is directed to a statutory method.

Example 2:

An application discloses a vehicle wheel alignment system comprising a vehicle station used for vehicle testing, a set of optical sensors for measuring vehicle wheel alignment angles, an automated tool for adjusting wheel angles, and a computer station. Aligning vehicle wheels is a process which includes measuring and adjusting a number of wheel angles, such as camber, caster and toe angles, as well as the steering axis inclination. The computer runs software which compares angles measured by the optical sensors with manufacturer-recommended specifications stored in a database and produces an output signal which instructs the automated tool to perform a synchronized adjustment of any wheel angles that are outside predetermined limits. The automated tool is a single unit comprising several modules, with each module being capable of adjusting one of the wheel angles.

The prior art search reveals that the following features are known:

- a vehicle station used for alignment of vehicle wheels,
- measuring wheel alignment angles using a set of optical sensors,
- inputting the measured values to a computer,
- searching a database to determine if the measured angles meet manufacturer recommendations,
- the use of a computer to calculate required wheel angle corrections; and
- a tool for adjusting wheel angles.

The prior art does not disclose an automated tool for the synchronized adjustment of multiple wheel angles, comprising several modules in a single unit wherein each module adjusts a specific wheel angle.

Claims:

1. A method for vehicle wheel alignment comprising the steps of:
    a. measuring vehicle wheel alignment angles using a set of optical sensors,
    b. inputting the measured alignment angle values into a computer,
    c. searching for corresponding manufacturer recommended wheel angles stored in an electronic database,
    d. calculating differences between the measured values and the corresponding manufacturer recommended angles,
    e. producing a signal to actuate an automated tool for angle alignment, said signal being based on the calculated differences, and
    f. synchronously aligning wheel angles on the vehicle using the actuated tool.

2. A system for vehicle wheel alignment comprising:
    a. a set of optical sensors for measuring vehicle wheel alignment angles;
    b. an automated tool for the synchronous adjustment of vehicle wheel angles, the automated tool being a single unit comprising several modules, with each module being capable of adjusting a specific wheel angle; and
    c. a general purpose computer in electronic communication with the optical sensors and the automated tool, wherein the computer comprises:
        i) means for receiving inputted data,
        ii) means for retrieving manufacturer recommended wheel angle values from an electronic database,
        iii) means to calculate differences between the measured values of the vehicle wheel alignment angles and the manufacturer recommended angles, and
        iv) means to output a signal based on the calculated values to actuate the automated tool in order to synchronously align the vehicle wheel angles.

3. A method for calculating a vehicle wheel angle condition comprising the steps of:
    a. inputting measured values of vehicle wheel angles into a computer,
    b. searching for corresponding manufacturer recommended wheel angles stored in an electronic database,
    c. calculating differences between the measured values and the recommended values, and

d. displaying the calculated angle differences on a computer display.

4. A system for calculating a vehicle wheel angle condition comprising:
    i) an input means for inputting measured values of vehicle wheel angles,
    ii) a processor means for searching for corresponding manufacturer recommended angles stored in an electronic database and for calculating differences between the measured values and the manufacturer recommended angles, and
    iii) an output means for displaying the calculated angle differences on a computer display.

Analysis: Claim 1 defines a method involving the application of physical steps to solve a technological problem - how to align the various wheel angles synchronously rather than sequentially. The method, when considered as a whole, is statutory in form. The prior art discloses measuring wheel alignment angles, comparing the measured values to a database and performing the alignment sequentially in respect of each angle. There is no prior disclosure of performing the alignment synchronously. The patentability of the method depends on whether the examiner considers step f, which is novel, to also be inventive. Since the patentability of this claim depends on whether a statutory step is considered to be inventive, the critical assessment can be made under section 28.3 of the *Patent Act*.

Claim 2 defines a system to perform the method of claim 1. If the system has been specifically adapted in order to perform the method (in this case, the use of multiple modules in a single unit suggests that this is the case), then its patentability depends on the same factor of inventiveness as claim 1. As noted in 16.02.03, a machine specifically adapted to perform the entirety of a patentable method is patentable.

Claim 3 defines a method for performing calculations in order to obtain information. By its form, the claim includes physical steps that could, in theory, be patentable. It is clear, however, that the technological aspects of each step (how to input data on a computer, how to search databases, how to solve a simple algebraic equation on a computer, how to display a result) are known and form part of the common general knowledge in the art. In view of the common general knowledge in the art, it can be readily concluded that, in substance, the invention in claim 3 amounts to a mental method performed by a computer. Following 16.02.01, the addition of a computer does not make a non-statutory method statutory. Having determined that no statutory subject-matter has been contributed, the defect associated with claiming a mental method is identified under section 2 of the *Patent Act*.

Claim 4 defines a computer capable of performing the method of claim 3. For it to be patentable, some technological advance would have to have been made in the operation of the computer itself. The claim defines “an input means for inputting”, “a processor means for searching ... and calculating" and "an output means for displaying". These are the discrete statutory elements of the system and represent hardware and software components capable of performing the stated functions. The remaining features of the claim pertain to what values are to be inputted, looked up, used in the calculations and displayed. These features have purely intellectual significance and do not define how the system is operated as a technological entity. As drafted, it is self-evident that the technological functionality required of the defined statutory means is present in a general purpose computer. The claimed matter lacks novelty in view of the common general knowledge in the field of computers and does not comply with section 28.2 of the *Patent Act*. The claim can also be considered defective under section 2 of the *Patent Act* for attempting to distinguish over known subject-matter by features having a solely intellectual significance.

16.04 Utility

An invention must be useful, in the sense of doing whatever was promised by the inventors. The utility of the claimed subject-matter must be established by demonstration or sound prediction, and this subject-matter must be operable to produce the promised result in a manner that is controllable and reproducible.

A computer is generally considered to be capable of reproducibly performing whatever operations its hardware and programming enable. The utility of a computer-implemented invention is not guaranteed by this fact, however. Even where the components of the computer are working as intended, the invention as a whole may require other elements for its proper operation.

Where the judgement or interpretative reasoning of an operator is implicated in the proper operation of the claimed invention, such as deciding on suitable computer-managed operations through the exercise of judgement and reasoning, the criterion of reproducibility will not be satisfied. Where an operator's input is required, but there is no judgement associated with the input, the need to rely on the input does not cause a lack of reproducibility [see section 12.08.02 of this manual].[4]

Where a computer-implemented method is being claimed, it must be unambiguously clear which steps of the method are being carried out on or by a computer [see 16.08.01].

16.05 Sufficiency

The general requirements for a sufficient disclosure of an invention are detailed in Chapter 9 of this manual, and apply equally to computer-implemented inventions as to any other.

Certain aspects of a correct and full description of a computer-implemented invention warrant particular attention, and are discussed in the following sections.

16.05.01 Written description and enablement

In accordance with subsection 27(3) of the *Patent Act*, the specification must correctly and fully describe the invention. In practice, this requirement relates to the description, which must support the claims in accordance with section 84 of the *Patent Rules*.

The two requirements of a description are i) that it disclose in clear and unambiguous terms the nature of the claimed invention (written description requirement) and ii) that it provide any teachings necessary to allow a person skilled in the art to operate the claimed invention (enablement requirement). A person skilled in the art must be able to understand, in view of the specification alone when read in light of their common general knowledge, what the invention is, what it does, and how to make it work.

The level of description necessary will depend on the facts of each case. In general, where aspects of common general knowledge are referred to, it may not be necessary to do more than identify a well-known element or technique forming part of this common stock of information. Where specific information is required that does not form part of the common general knowledge, this must be explicitly provided. For example, if certain hardware and software are known in the art at the date of invention, it will be obvious that they can be used to achieve known or predictable results or perform known or predictable operations. It may be possible to describe and enable those aspects of the invention that relate to this known hardware or software simply by identifying the particular hardware or software element to be used and the known or predictable result to be achieved. In contrast, if the desired result requires a novel and unobvious application of hardware or software, a greater level of detail regarding how this result is to be achieved would be necessary.

Where a claim defines the invention in terms of means-plus-function statements, the nature of the means, and where applicable how they are arranged to provide the stated functionality, must be clear to the person skilled in the art. The level of description necessary to correctly and fully describe the means, and their arrangement where applicable, will depend on the state of the common general knowledge in the art. Where limited description is provided, this is taken as an indication that the applicant (rightly or wrongly) considers that the selection of suitable means to perform the stated function would be readily apparent to a person skilled in the art.

Computer-implemented inventions are often described in terms of a flow chart that illustrates the algorithm or logic tree on which the operation of the invention is based. Typically, the flow chart will set out the operations performed by a computer. Flow charts are diagrams having a series of boxes, each representing a state or a step in an algorithm, and arrows that interconnect these boxes to describe the order or relationship of the various steps.

It will often be the case that the algorithm or logic performed by the computer lie at the heart of the invention. In such circumstances, a full description of the algorithm or logic tree should be provided. Where the algorithm or logic is described by reference to a flow chart, presented as a drawing, a written explanation of the flow chart is necessary to provide support for any claims that refer to the algorithm or logic.

In order to successfully practice the invention, it is necessary for the person skilled in the art to be able to put each step in the flow chart into operation. For the description to be enabling, the person skilled in the art must be able to do this without recourse to inventive ingenuity or undue experimentation. The flow chart, and any accompanying description, must therefore provide any information necessary to enable the algorithm to be so practised.

The amount of written description necessary to properly describe and enable an algorithm depends on the relationship of each step to the common general knowledge. Where the algorithm invokes well-known operations, it may be that very little or no specific description is necessary for the purposes of proper description or enablement. If, in contrast, the specific operations necessary to enable a step in the algorithm would not be obvious to the person skilled in the art, these operations would need to be fully described.

Furthermore, if the common general knowledge of the person skilled in the art would lead them to attempt to enable the algorithm in ways that would not in fact work, the description should provide sufficient instructions to allow the person skilled in the art to arrive at operable embodiments and avoid inoperative ones.

Where very little explanation is given regarding how a step in a method is to be implemented by a computer, this will generally be understood as an indication that the applicant, rightly or wrongly, does not consider the implementation of that step to require inventive effort on the part of the person skilled in the art.

16.05.02 Source code or pseudocode

Source code or pseudocode may be provided as part of the description of a computer-implemented invention, but will generally not be considered, by themselves, to provide a full and enabling description of an invention.

Where source code is provided, it must be remembered that the significance of the commands used in specific code may depend on the intended platform, and the code itself will generally not be a clear and unambiguous description of the invention.

Pseudocode refers to a semi-structured, natural language explanation of the functioning of an intended program, and may be used as an alternative to a flowchart to provide a set of instructions with a logical sequence but which do not follow the syntax of any particular programming language. Pseudocode will therefore usually have a greater value in describing an invention than source code in a specific programming language. However, in the same way that a flowchart will usually require an accompanying description in order to fully describe an invention, pseudocode alone will typically not be sufficient to provide a full and unambiguous description of an invention.

16.05.03 Common general knowledge and programming

The activities required to reduce a specific series of logic instructions to a computer code are considered to form part of the common general knowledge of a skilled programmer. It is, therefore, typically not necessary for an inventor to describe how to write computer code, either in general or in respect of a specific computer language.

Where the algorithm to be written out as lines of code only invokes well-known operations, or if specific and unobvious logic operations are required, where these have been clearly described, the act of expressing the specific commands as lines of code is considered not to require inventive ingenuity or undue effort.

Where the description only discloses in broad terms what the program is intended to do, and it would not be clear to the person skilled in the art in view of their common general knowledge what the required operations are or the logic necessary to enable specific required operations, then the skilled programmer has not been given sufficient instructions to create the necessary code. To create a working program, the programmer would first have to exercise ingenuity in order to solve the problem of reducing the concepts disclosed to a series of practical instructions (i.e. would need to design the program; see 16.03.01).

16.06 Novelty

As with every invention, in order to be patentable a computer-implemented invention must not be anticipated by prior art that is relevant under section 28.2 of the *Patent Act*.

To be anticipatory, a single prior written disclosure, when understood in light of the common general knowledge, must both provide a written description of the claimed invention and sufficient instructions to enable the invention to be practised by the person skilled in the art without recourse to inventive effort or undue burden.

In considering whether a claimed invention is anticipated, its essential elements must be compared to those taught in a single prior disclosure. If all its essential elements were previously disclosed, the invention is anticipated. The essential elements of an invention are those that have a bearing on what the invention will do and how it does it (i.e. on its practical and promised utility) [see section 13.05.03 of this manual].

When considering a computer device (*machine*) claim, the effect of any commands being implemented by software must be carefully considered in order to determine if they lead to a technological effect relevant to the promised utility of the device. If so, those commands are essential elements of the device, and must be considered during the novelty analysis. If the commands are simply an application of functionality the machine was already known to possess, they are not considered to be essential elements of the machine itself.

16.06.01 Anticipation by prior use

Although the majority of prior art consists of prior written disclosures, a prior sale or use of an invention can also amount to an anticipation, provided it makes available information which describes the claimed invention and amounts to an enabling disclosure.[5]

With regard to computer-implemented inventions, software that was available to the public prior to the claim date can be considered as prior art. To be considered to have disclosed the claimed invention, the software must provide to the person skilled in the art information sufficient to comprehend the invention.[6] The use of a product makes the invention part of the state of the art only so far as that use makes available the necessary information.[7] The information made available must be such that if the person skilled in the art were to write down that information, they would have drafted a clear and unambiguous description of the claimed invention.[8]

Thus, if the claimed invention is defined broadly using functional language, any prior art software that achieves the same function could be anticipatory. In contrast, if the claimed invention defines a particular method for arriving at a specific result, prior art software would only be anticipatory if it could be established, on the balance of probabilities, that it was using the same method for arriving at the result.

As was noted in *Baker Petrolite Corp. v. Canwell Enviro-Industries Ltd.*, in determining whether a publicly available product anticipates a claimed invention, the ability of the person skilled in the art to reverse engineer the product “in accordance with known analytical techniques” may be relevant.[9] Therefore, where relevant, the ability of the person skilled in the art to reverse engineer software, without inventive effort, in order to ascertain what method it implements must be considered. Note that what is considered is the ability to reverse engineer, such as by decompiling; it is not necessary to establish that the product was actually reverse engineered.[10]

In considering whether anticipation by prior sale or use of an invention has occurred, the grace period provided for in paragraph 28.2(1)(*a*) of the *Patent Act* applies in respect of any making available of the invention by the applicant or by a person who obtained the relevant knowledge directly or indirectly from the applicant.

16.07 Ingenuity

As with every invention, in order to be patentable a computer-implemented invention must not be rendered obvious by prior art that is relevant under section 28.3 of the *Patent Act*.

Obviousness is evaluated in view of the overall state of the art contained in the prior art, when this is considered as a whole in light of the common general knowledge of the person skilled in the art. A claimed invention must be the result of ingenuity, and a conclusion of obviousness is equivalent to a conclusion of lack of inventive step. To be considered obvious, the teachings present in the prior art must be sufficient so that, if combined, they would lead to the claimed invention. Furthermore, it must be uninventive (obvious) to combine the necessary teachings.

As with the assessment of novelty, the assessment of obviousness is based on the essential elements of the claimed invention. There is nothing inventive in adding a non-essential element to an invention, since by definition the non-essential element is irrelevant to the invention's successful operation.

It is considered obvious that computers can be used to automate many manual operations, and the idea of automating a manual process is, in the absence of reasons to conclude the contrary, considered to be uninventive. The inventive step necessary to support a claim to a computer-automated version of a known manual method therefore must typically be found in the solution to specific challenges attendant to enabling the automation.

Where a computer-implemented invention aims to achieve a new unitary result through the use of a combination of known hardware and software, an inventive step may exist by virtue of the recognition that the combination will achieve that result. If, in contrast, using the hardware and software together merely results in a predictable outcome, the alleged invention is a mere aggregation.

16.08 Claims

A computer-implemented invention is typically claimed as a *machine*, a method (an *art* or *process*) or a *manufacture* (computer-readable medium). As with any type of claim, a claim to a computer-implemented invention must meet the requirements of, *inter alia*, subsection 27(4) of the *Patent Act* and section 84 of the *Patent Rules*.

16.08.01 Computer-implemented method claims

Where a claim is directed to a method that is to be implemented in whole or in part by computer, it must be unambiguously clear which steps of the method are being carried out by the computer.

Specifying in the preamble that a method is "computer-implemented" implies that some, but not necessarily all, steps of the method are performed by a computer. Where, in view of the specification as a whole, a given step can be understood as being performed either by a computer or by a person, it should generally not be presumed that the claimed method requires that step to be performed by a computer.

16.08.02 Computer claims

Where a claim is directed to a *machine*, it must be defined in terms of physical components.

Many computer claims will define the device in terms of means statements that set out what the device will do. Where a means statement is understood to be a software means, it must be specified that the software is stored on a physical memory. This can be done in the claim itself or in the description, with due regard being given to the need for the language of the claim to be clear, concise and unambiguous.

In some cases, it is possible that the means referred to in a means statement can be either hardware or software. In such cases, it may be most convenient to specify in the description that the means statement refers to either hardware or software on a physical memory.

16.08.03 System claims

The term *system*, depending on the context in which it is used, may refer to a *machine* (a device or apparatus, or a network of devices or apparatuses), a computer program or set of computer programs (e.g. a *database management system* or an *operating system*), or a *method*. Consequently, care must be taken to ensure that its intended meaning in a given context is unambiguous.

In the computer arts, where it is not clear that something else is meant it may be presumed that the term *system* refers to a *machine*.[11]

Regardless of which meaning is intended, it must be clear which category of *invention* the claimed subject-matter is meant to belong to. Where the claimed *system* is not a *machine*, it may be necessary to explicitly define that it is, for example, a software product or *method* in order to comply with subsection 27(4) of the *Patent Act*.

16.08.04 Software product claims

A computer program (software), when claimed *per se*, is considered by the Office to be an abstract scheme, plan or set of rules for operating a computer [see section 12.06.02 of this manual], and consequently not to be an invention within the meaning of section 2 of the *Patent Act*.

Under certain circumstances, software can be claimed by directing the claim to a physical memory storing the computer program. A claim to a physical memory falls within the category *manufacture*.

In defining a software product, the form of the claim is important. The preamble must clearly direct the claim to a physical product limited by the computer program stored thereon, and not to a computer program limited by having been stored on a memory. Thus, the preamble "a physical memory having stored thereon..." directs the claim to a statutory embodiment, whereas "a computer program stored on a physical memory" directs the claim to a computer program and thus to excluded subject-matter.

Furthermore, it must be explicitly defined that the computer program is present as machine-executable code. Only machine-executable code can change the technological functionality of the physical memory storing the program. Non-executable code is considered to be mere descriptive matter [see section 12.06.04 of this manual].

Where the computer program would cause the device it controls to provide a technological solution to a technological problem, the "software-modified physical memory" is a single discrete element. Where the program is novel and inventive, the claim will include a statutory contribution [see section 12.06.07 of this manual]. These, then, are the circumstances under which a software product comprising a physical memory storing executable code can be patented.

Example:

1. An application is directed to a computer-implemented method for determining a channel assignment in a Code Division Multiple Access (CDMA) network. The method improves CDMA networks by determining CDMA channel assignments according to predetermined constraints. It has been discovered that appropriate predetermined constraints improve efficiency in the network.

   The prior art search reveals that the following features were known from D1:
   - CDMA network with channel assignments
   - A computer-implemented method for performing the channel assignment

   D1 does not disclose the use of predetermined constraints to modify channel assignments

Claims:

1. A computer-implemented method for optimising channel assignments in a CDMA network, comprising the steps of:
a. performing an initial channel assignment;
b. comparing the channel assignment with predetermined constraints to determine a difference;
c. modifying said initial channel assignment in accordance with said difference; and
d. changing the channel assignment in the CDMA network in accordance with the modified channel assignment.

2. A computer program for optimising channel assignments in a CDMA network according to the method of claim 1.

3. A computer readable memory having recorded thereon statements and instructions for execution by a computer, said statements and instructions comprising:
a. code means for performing an initial channel assignment;
b. code means for comparing the channel assignment with predetermined constraints to determine a difference;
c. code means for modifying said initial channel assignment in accordance with said difference; and
d. code means for changing the channel assignment in the CDMA network in accordance with the modified channel assignment.

4. A computer program product comprising a computer readable memory storing computer executable instructions thereon that when executed by a computer perform the method steps of claim 1.

Analysis: Claim 1 defines a technological method comprising physical steps, and is therefore statutory in form. Assigning channels in a CDMA network according to the method results in an improved communications network; the method therefore provides a technological solution to a practical problem and the steps pertaining to the predetermined constraints are technologically distinct from similar steps performed without the constraints. The prior art does not disclose the feature of using predetermined constraints to modify an initial channel assignment in a CDMA network. Presuming that the examiner determines this to be an inventive feature, at least one physical step in the method will have been contributed. The claim would then include a statutory contribution and be allowable. Note that, to avoid indefiniteness, it would be necessary in an actual claim to define the actual "predetermined constraints" being relied on.

Claim 2 defines a computer program *per se* and is therefore directed to non-statutory subject matter by its form. The claim is objected to under section 2 of the *Patent Act*.

Claims 3 and 4 are alternative ways for defining a computer product. Both are acceptable in their form. To be patentable, the physical memory must be considered to be technologically distinct from other physical memories. This is considered to be the case where the computer program stored on the memory would cause a computer running the program to itself be a technological solution to a technological problem. A computer programmed in a novel way to implement the entirety of an inventive method is patentable in its own right [see section 12.06.06*b* of this manual]. Where the programmed device would be patentable, a physical memory storing the program as computer executable code is also patentable. Therefore, where the method of claim 1 would be patentable, either of claim 3 or claim 4 would also be allowable.

16.08.05 Means statements in claims

A "means" statement defines some part of an invention in terms of a *means* suitable for achieving a result, rather than by explicitly defining those specific things that would yield the result. Means statements are not objectionable *per se*, provided the claim meets all the requirements of the *Patent Act* and *Patent Rules*.

In order for a means statement to be properly supported, the description must describe what types of means are contemplated by the inventor unless this would be obvious to the person skilled in the art in view of their common general knowledge. Where it would not be obvious to the person skilled in the art which *means* fall within the scope of a defined means statement, the claim may be defective for lack of proper support or for indefiniteness. A *means* statement may refer to hardware or to software, and it should be clear in the context of the claim what the means statement refers to.

In the computer arts, the term "means" is often used in reference to a computer running software. Unless the context of the claim precludes this interpretation, a *means* statement that encompasses software may be understood to refer to software stored on a physical memory and being executed by a processor.

16.08.06 Mixed claim types

The subject-matter of a claim must belong to a category of invention as defined in section 2 of the *Patent Act*. The elements used to define the subject-matter must consequently be of a type appropriate to that category of invention.

Where a claim in one category of invention (e.g. a *machine*) defines its subject matter in terms of elements from another category (e.g. *method* steps), there is a risk of ambiguity over the intended subject-matter.

Where a claim is directed to a *machine*, it must define its subject-matter in terms of structural components whereby the machine can be distinguished from all other machines. Given that computers are often defined in terms of means statements that provide functional limitations to the machine, care must be taken to ensure these means statements can be understood to be physical components [see 16.08.02].[12]

Where a claim is directed to a *method* of using a device, it must include at least one step whereby the device is applied to the task at hand. A claim simply reading "*A method of using the device of claim 1.*" may be considered indefinite, for example, since the manner by which the device is used has not been defined.

Note that the "product-by-process" claim type defines a product wholly or partly in terms of the process by which it is produced. It is not a format for defining a product in terms of the method for which it will be used.

16.09 Special topics

This section addresses specific types of subject-matter for which particular attention, elaboration or clarification was considered appropriate.

In the following sections, the example claims are analysed following the approach set out in Chapter 13 [see, in particular, section 13.05 of this manual and its various subsections]. Furthermore, the analyses focus primarily on the question of whether a statutory contribution exists on the presumed facts of each example. In attempting to provide simplified examples, little consideration has been given to the question of enablement. Many of the example claims are defined in terms of broad functional statements ("means for" statements). In practice, whether these are properly supported would depend on the degree of disclosure and on the common general knowledge in the field [see section 16.05].

16.09.01 Graphical user interfaces

A "Graphical User Interface" (GUI), as the name implies, refers to a type of interface for enabling a user to interact with a computer or a computer-based device. While early computers used command line interfaces that required the user to enter textual commands to control a computer, graphical user interfaces enable the user to interact with the computer via visual elements such as icons, buttons, menus, toolbars and other graphical screen elements.

The term GUI is considered by the Office to refer only to the arrangement of visual elements that will be displayed on a screen, and not to include any of the hardware or software components that may be required to generate the graphical user interface or to make it functional. A GUI as such is consequently considered to be information, that when displayed on a screen is subject to the practice set out in section 12.06.04 of this manual.

An invention is considered to be a solution to a practical problem, which the Office considers to imply a "technological solution to a practical problem" [see section 13.05.01 of this manual]. Features having purely intellectual or aesthetic significance are not statutory subject matter and cannot provide a statutory contribution [see section 12.06.01 of this manual]. Any display of information wherein the sole contribution is in the information itself amounts to non-functional descriptive matter, and is not a patentable contribution [see section 12.06.04 of this manual].

The specific arrangement of graphical elements on a screen, or in other words the visual design that defines a graphical user interface, is viewed by the Office as not constituting a patentable contribution where the visual design of the graphical user interface does not provide a technological solution to a practical problem. Rather, it is viewed as having purely aesthetic significance and amounts to non-functional descriptive matter.

However, the presence of a graphical user interface does not exclude an invention from patentability if the criteria for patentability are satisfied. A GUI that has been integrated with statutory subject matter may be patentable. Claims including a GUI must be directed to one of the categories of invention, as defined in section 2 of the *Patent Act*.

Example 1:

An application discloses a portable device that allows a user to read an electronic book. The device comprises a touch screen, and displays the electronic book using an efficient graphical user interface that provides buttons for frequently used operations at the top of the screen, hyperlinks to other content within the book on the left of the screen, and a central frame for displaying the content of the book. The device also allows the user to enter personal notes at any location within the content of the electronic book. The personal notes are stored within XML tags that are embedded within the content, and a graphical icon is displayed at the location of each XML tag. The user is able to view stored personal notes by clicking on the relevant graphical icon. The touch screen is able to recognize advanced user touch commands, and the device comprises software to interpret such touch commands and perform specific functions.

The prior art search reveals that the following features are known from D1:

- displaying an electronic book on a portable device having a touch screen;
- displaying a graphical user interface including common elements such as hyperlinks, buttons, scrollbars, content frames and input boxes;
- the touch screen allows the user to point, click and drag items on the GUI.

The prior art does not disclose the efficient GUI arrangement of this application, the feature of storing personal notes using XML, or the feature of recognizing advanced touch commands.

Claims:

1. A graphical user interface for a portable electronic book reading device having a touch screen, the graphical user interface displaying on the touch screen:
- a series of buttons appearing at the top of the screen representing frequently performed operations;
- a region appearing at the left hand side of the screen containing a plurality of hyperlinks to other content within the electronic book;
- a scrollbar appearing at the right hand side of the screen;
- a central frame displaying a page of content from the electronic book;
- an input box appearing at the bottom of the screen for accepting user input.

2. A portable electronic book reading device having a touch screen displaying the GUI of claim 1.

3. A computer readable medium comprising computer instructions that when executed by a portable electronic book reading device having a touch screen displays the GUI of claim 1.

4. The computer readable medium of claim 3 further comprising instructions that when executed enable the portable electronic book reading device to:
- accept a text input from the input box representing a user's personal notes;
- identify a specific location within the page currently being displayed on the screen;
- embed the personal notes within the content of the electronic book at the identified location using predefined XML tags;
- parse the content of the electronic book to identify all embedded XML tags and to display a graphical icon at the location of each XML tag; and
- display the personal notes embedded within an XML tag upon user request.

5. The portable electronic book reading device of claim 2, wherein the touch screen is configured to recognize a pinching motion touch command by the user, and wherein the touch command enables the user to flip to the next or previous page of content by performing the touch command and dragging the page to the right or left hand side of the touch screen.

Analysis: Claim 1 defines a graphical user interface *per se* and is therefore directed to non-statutory subject matter by its form. The claim is objected to under section 2 of the *Patent Act*.

Claim 2, in contrast, is directed to a device and is therefore not objectionable in terms of its form. Upon closer examination, it is evident that claim 2 contains both statutory and non-statutory features. The portable device and the touch screen are two statutory features, while the arrangement of screen elements as defined in the claim is a non-statutory feature. The touch screen provides a technological limitation to the portable device, so the two are considered to be a single discrete element of the claim. However, the arrangement of screen elements does not provide a technological limitation to the portable device having a touch screen, and is therefore considered to be a second discrete element of the claim. In order to determine if the subject matter of claim 2 includes a statutory contribution, the prior art features disclosed in D1 must be compared to the statutory discrete element recited in the claim. Given that the prior art discloses a portable electronic book reading device having a touch screen, this feature does not form part of the contribution of the claim. It is not necessary to assess whether the arrangement of screen elements has been contributed, since it is a non-statutory discrete element and cannot itself result in a statutory invention. Following the contribution analysis, it is determined that claim 2 does not contain a statutory contribution. An objection under section 2 of the *Patent Act* on the basis of the non-statutory subject matter would be appropriate, since this matter is the point of the invention.

Claim 3 defines a computer program on a physical medium. The software allows the GUI of claim 1 to be displayed. The claim does not define any features that define a technological solution to a technological problem. The GUI of claim 1 remains a discrete element of the claim, and the physical memory comprising software that enables information to be displayed is a second discrete element of the claim. It is clear from D1 that software for displaying information was known in the prior art, and the memory having such software stored on it is therefore not part of the contribution. The claim can be objected to in the same manner as was claim 2.

Claim 4 is again directed to a computer program on a physical medium, but recites additional features allowing the user to embed personal notes at specific locations within the content of the electronic book using predefined XML tags, and to subsequently display the personal notes upon request. These features work together to modify the way in which the device executing the instructions stored on the computer readable medium operates, in such a way that they provide new functionality to solve a practical problem. In this case, the practical problem being how to enable the user to store and retrieve personal notes at specific locations within the content of an electronic book. Since the device itself would provide a technological solution to a technological problem and would be considered statutory, the computer readable medium storing the instructions that would control the device is also considered to be statutory [see 16.08.04]. If the examiner determines, based on the state of the art at the claim date, that the feature of embedding notes within the content of an electronic book using XML tags is novel and inventive, then this would be regarded as a statutory contribution and the claim would be allowable.

Claim 5 recites an additional feature of recognizing a specific touch command performed by the user of the touch screen, and performing a specific functionality based on such a touch command. Although the prior art touch screen allowed the user to point and click, it did not have the ability to recognize a complex motion such as a pinching motion similar to how a person would flip a page in a physical book. This feature is regarded as a technological feature providing new functionality to solve a practical problem, which is in this case to provide functionality to the touch screen to enable the user to conveniently browse through an electronic book using normal hand gestures. Since this feature is a technological modification to the portable electronic device, the overall modified device is now considered to be a single discrete element. If the examiner determines that this functionality is novel and inventive, a statutory contribution would be present in the claim and it would be allowable.

Example 2:

An application discloses a system for controlling the operation of network devices. Each device stores self-describing information detailing what type of device it is, and what control options are available to network users. A graphical user interface displays unique icons representing each device on the network, as well as a customized menu for each device showing available control options. The unique icon and the available control options are retrieved from each device on the network dynamically, resulting in a graphical user interface that accurately reflects the network at all times, even when changes are made to the network or the network devices.

The prior art search reveals that the following features were known from D1:

- A system for controlling network devices
- The system uses a GUI to display the devices and the available control operations

The GUI of D1 is static and does not obtain self-describing information from the devices.

Claims:

1. A graphical user interface generated by a computer program for facilitating the control of devices located on a network, comprising:
- a first graphical element representing each device located on the network; and
- a second graphical element representing available control options for each of the devices,
wherein the computer program dynamically retrieves the graphical representations and available control options from self-describing information stored within each of the devices.

> 2. A computer-implemented method for interacting with devices located on a network, comprising:
> - displaying a first graphical element representing each device located on the network;
> - displaying a second graphical element representing available control options for each of the devices; and
> - dynamically retrieving the graphical representations and available control options from self-describing information stored within each of the devices.

Analysis: Claim 1 is directed to a GUI, and further defines that the GUI is generated by a computer program and that program will dynamically retrieve certain information from devices attached to the computer. The claim is directed to excluded subject-matter by its form, however, and is objected to under section 2 of the *Patent Act*. The presence of the computer program feature indicates how the GUI is generated and modified, but the claim itself is still directed to a GUI *per se*.

Claim 2 is directed to a computer-implemented method wherein graphical elements are displayed and wherein the content of the display is dynamically updated by the computer program that generates the GUI. This method of controlling the operation of the computer provides a technological solution (dynamic querying) to the practical (technological) problem of having a current list of control options available for each peripheral device attached to the computer. The method enables the graphical user interface to be dynamically updated as devices on the network are added, removed or modified, and results in a more efficient system for controlling network devices. The method is statutory in form. Each step in the method includes both a statutory discrete element (displaying graphical elements or dynamically retrieving information) and a non-statutory discrete element (the information that is displayed or retrieved, and which does not limit the technological aspects of displaying or retrieving). The statutory steps of displaying graphical elements and dynamically retrieving information from the peripheral devices would be examined to determine if the overall method is both novel and inventive over the prior art. Since the steps operate together to provide a unitary result, they are compared to the prior art in combination.

Note that if the method is considered to be novel and inventive, a claim to a device operating the method or to a physical memory storing the software that enables the method would also be allowable.

16.09.02 Data structures

A data structure is a format for organizing and storing a collection of related data items to suit a specific purpose. A particular data structure may enable or facilitate a specific set of operations to be performed on the data items easily and efficiently, for example to improve the performance of computer programs and minimize the consumption of computer resources. Examples of data structures are arrays, records, linked lists, stacks and trees.

The Office considers a data structure to be an abstract idea or plan for organizing data items, and not to include the physical medium upon which the data structure is to be stored. A data structure *per se* is consequently considered to be disembodied and not an invention within the meaning of section 2 of the *Patent Act* [see section 12.06.02 of this manual]. For a data structure to have an impact on the patentability of a claimed invention, it must in some way limit the technological nature of a statutory element in the claim.

Example:

An application discloses a networking system that guarantees a quality of service for a networking connection, wherein the system comprises networking equipment that is used to transmit data packets across a network. The data packets include a quality of service indicator that is read by other networking equipment along the path of the transmission, such that the networking equipment will prioritize delivery of packets with a higher quality of service guarantee.

The prior art search reveals that the following features are known from D1:

- Networking equipment for transporting data packets from source to destination
- Data packets having a header and a payload for transporting data through a network
- Packet header containing control bits including addresses and error correction bits

The prior art does not disclose prioritizing packet delivery based on a quality of service indicator within the packet header.

Claims:

1. A data structure for transmitting data over a network with a guaranteed transmission quality of service, the data structure being a packet comprising:
- a payload containing the data to be transmitted;
- a header containing control bits for managing the transmission of the data, including:
    - a source address indicating the source of the data;
    - a destination address indicating the destination of the data;
    - error detection and correction bits;
    - an 8-bit quality of service indicator that is used by networking equipment to prioritize delivery of packets.

2. A memory for storing data for access by an application program being

executed on a data processing system, the memory storing the data structure of claim 1.

3. A computer-implemented method for data transmission with a guaranteed quality of service comprising:
    a) transmitting and receiving data over a network using data packets according to claim 1; and
    b) prioritizing the delivery of data packets on the basis of the quality of service indicator.

Analysis: Claim 1 defines a data structure *per se*, and is therefore directed to non-statutory subject matter by its form.

Claim 2, in contrast, is directed in form to a physical memory, and consequently to a statutory *manufacture*. The data stored on the memory does not alter the technological character of the memory, and therefore is a discrete element of the claim. The claim, consequently does not include a statutory contribution. Since the data structure is the point of the invention, an objection could be presented under section 2 of the *Patent Act* on the basis of a contribution analysis. Note that the conclusion differs from that which could be reached if the physical memory were storing executable computer code that made use of the structure to render a computer more efficient or reliable.

Claim 3 defines a method for transmitting and receiving data wherein the system can prioritize data based on its quality of service indicator. The data structure is made use of to control the manner by which data packets are transmitted, and this changes the technological character of step b). The step of prioritizing delivery is understood to involve an analysis of the packets, an evaluation of network traffic and available bandwidth, possibly storing certain packets temporarily, etc. Depending upon the state of the art and the common general knowledge in the field, such details might need to be defined in an actual claim. Both steps in the method are technological in nature, and the method provides a technological solution to a practical problem and is statutory. If the data structure and its technological effect are found to be novel and inventive, the method would be patentable.

16.09.03 Databases

In general terms, a database refers to a collection of information organized so that it can be stored, searched and retrieved easily. Computer databases can be implemented in many forms, the simplest being to store information in a text file in a specific format (a data structure) to enable the information to be subsequently retrieved. More advanced implementations employ specialized software, often referred to as a *database management system*, to control access to the stored information. Examples of common *database management systems* in use today include Microsoft™ Access™, MySQL™, and Oracle™.

The Office interprets a database to be solely a collection of information, and not to include the physical medium upon which the database is stored. A database *per se* is consequently considered to be disembodied and not an invention within the meaning of section 2 of the *Patent Act* [see section 12.06.02 of this manual]. Where a database, as a feature of a claim, limits the technological nature of a statutory element in the claim it can result in a statutory contribution.

A *database management system* is generally understood in the art to be a computer program [see 16.08.03 on *system* claims]. A claim to a *database management system* computer program is not directed to a statutory invention whereas a claim to a physical memory storing a *database management system* defines, in form, a statutory *manufacture* [see 16.08.04].

Example:

An application discloses a distributed database system to reduce the load on database servers in a network. The same database is stored on multiple database servers. A common control server receives database access requests and distributes them among the multiple database servers. The control server keeps track of the load on each database server, and distributes requests in order to evenly distribute the load on the servers. The control server also periodically synchronises the data across the database servers during periods of lighter load, in order to maximise performance of the overall distributed database system. The application describes the use of the distributed database system for a web based social networking application.

The prior art search reveals that the following features are known from document D1:
- a web application using a distributed database system,
- that database access requests are distributed across the system, and
- that synchronisation is performed at set intervals

The prior art does not disclose the feature of a common control server keeping track of the load on the database servers in order to evenly distribute access requests and scheduling database synchronisation during periods of light server load, which results in improved performance of the overall distributed database system.

Claims:

1. A distributed database system comprising:

i) a plurality of database servers, each of which stores a copy of a database;

ii) a control server for controlling the distributed database system, wherein the control server comprises:

a) means for distributing received database access requests among the

plurality of database servers; and
b) means for performing database synchronisation to synchronise the content of the databases stored on the database servers.

2. The system of claim 1, further comprising:
iii) a web-based social networking application server;
wherein the distributed database is used to store for each user of the application:
- account information;
- profile information;
- a list of relationships between users; and
- messages sent and received by each user.

3. The system of claim 2, wherein the control server further comprises:
c) means for tracking the load of each of the plurality of database servers;
wherein the database access requests are distributed among the plurality of database servers according to the load of each server in order to evenly distribute the load among the database servers;
and wherein the database synchronisation is performed during periods where the database servers are experiencing a lighter than normal load.

4. A database comprising data related to a web-based social networking application, wherein the database includes for each user:
- account information;
- profile information;
- a list of relationships between users; and
- messages sent and received by each user.

Analysis: Claim 1 defines a plurality of servers i), wherein each server stores a copy of the database, and a control server ii) which comprises means to manage the system as a whole. The means statements are understood to be software stored on a physical memory and executed by the server's processor. The means both alter the technological operation of the control server ii), and the "software on a physical memory" means are therefore statutory elements of the claim. Equivalently, the "means-modified control server" may be considered a single discrete element of the claim. Each server i) is also a discrete element of the claim, as is the database (which does not provide a technological limitation to the server storing it). The patentability of the claim will depend on whether server ii) is found to be novel and inventive, since the servers i) are known and since the database is not a statutory feature of the claim. In view of D1, the server ii) would be considered novel. For the sake of this example, it is presumed that the server is found to be obvious in view of the cited prior art and knowledge in the field. The claim would therefore be objected to under section 28.3 of the *Patent Act*.

Claim 2 adds to the features of claim 1 a web-based social network application server, and defines the information stored for each user of the system. The application server is a statutory feature. In this example claim, there is insufficient information defined about the nature of any software on the server (i.e. how the social network application works) to determine whether the software would enable the server to solve a particular technological problem. In view of D1, which discloses a web-based application, it does not appear that the server iii) distinguishes the system over the prior art. The further feature of the claim, the specific information stored, is a non-statutory feature which does not provide a technological limitation to the server. The data is therefore a discrete element of the claim. To the extent it appears the applicant is asserting the data in order to distinguish the invention, an objection under section 2 of the *Patent Act*, referring to a contribution analysis, is warranted.

Claim 3 adds to claim 2 the additional feature of the system comprising means for tracking the load of the database servers, distributing database access requests according to this information in order to evenly distribute the load on the servers, and performing synchronization during periods of lighter than normal load. This means is, again, understood to be software stored on a physical memory and being executed by a processor. The means provides new technological functionality to the control server, and is a statutory "software on a physical memory" element of the claim. Equivalently, the means-modified server can be considered to be a single discrete element of the claim. If the examiner considers that the server having a means to provide the defined functionality is novel and inventive over the prior art, claim 3 would be considered to involve a statutory contribution and would be allowable.

Claim 4 defines a database *per se*, and is therefore directed to non-statutory subject matter by its form. The examiner will object to this claim under section 2 of the *Patent Act*.

16.09.04 Computer-aided design (CAD) programs

A computer-aided design program is a computer program specifically used in the design of objects and to perform simulations on designed objects before the final product is actually built, thereby leading to significant reductions in time and cost. CAD programs are used in many industries including architecture, automotive, electronics and computer animation among others.

CAD programs are typically not capable of independently performing the act of designing; rather they are tools that are used by designers to help with the design process. Inventions related to CAD programs will therefore usually focus on the functionality of the CAD program as a tool used to assist the designer, and not on their ability to independently carry out a design. While methods of designing may be viewed as schemes or mental processes, which are disembodied and not a practical form of an invention, CAD programs are tools that are used during the design process and may comprise a technological contribution.

A CAD program is a specialized type of computer program, and consequently the practices pertaining to computer programs apply to CAD programs.

Example 1:

An application discloses a computer-aided design tool for automatically performing integrated circuit placement, layout and routing. The tool starts its process by reading a netlist file defining all the components in a circuit schematic and their interconnections. The CAD program then performs the circuit placement, layout and routing using a hierarchical approach wherein simple circuit cells (sub-circuits within the overall circuit) are optimised first (this being the lowest level in the hierarchy), then larger sub-circuits (second and subsequent levels in the hierarchy), and so on until the overall circuit has been created. The program first scans the circuit to look for circuit cells, optimizes one example of each such cell and adjusts all others according to the optimized result. It then scans the circuit looking for larger cells and repeats the process until the overall circuit has been optimized. Since each higher level is optimised relying on the results of the lower level optimisation, fewer operations are needed overall in order to optimise the overall circuit. The approach also avoids "false minimum" optimisation results that can occur when the starting point of the optimisation is too unrelated to the actual optimised circuit. The optimised circuit can be displayed as an image, schematic, or as a control file for a computer-controlled fabrication process.

The prior art search reveals that the following features are known from D1:

- a CAD program for automated layout and routing requiring the manual placement by a user of all circuit cells before routing can be performed;
- a series of calculations that optimise the entire circuit iteratively.

The prior art does not disclose using a hierarchical approach to perform the layout and routing.

Claims:

1. A computer-implemented method for the automated optimisation of an integrated circuit design, comprising:
- reading a netlist file defining all circuit elements and interconnections;
- identifying circuit cells that are repeatedly instantiated in the design;
- creating a tree representation of the circuit cells and their hierarchical relationship;
- starting at the lowest level of the hierarchy:
    a) performing integrated circuit layout of the individual circuit cells;
    b) identifying the interconnections between the circuit cells;

c) performing placement and routing of the circuit cells while minimizing interconnection length and routing complexity;

- repeating steps a - c for all remaining levels within the hierarchy of the circuit, proceeding from the next lowest level to the highest level; and
- generating an output file containing the detailed layout and routing of the integrated circuit.

2. A computer-aided design program for performing the method of claim 1.

3. A computer readable memory having recorded thereon statements and instructions for execution by a computer to carry out the method of claim 1.

Analysis: Claim 1 defines a computer-implemented method whose object is the solution of a technological problem - how to provide an optimised layout of a circuit based on predetermined input parameters while avoiding "false minimum" results and minimising the number of operations necessary to optimise the circuit. The method as a whole therefore is statutory in its form. Each step in the method involves a series of computer operations for performing a specific task. The steps of reading the netlist file and generating an output file can be treated as discrete elements, since they do not limit the technological nature of the remaining steps. They represent known computer operations and are presumably not part of the contribution.

For this example, it is presumed that the hierarchical approach to optimising the circuit was not previously known and would not be obvious. The method provides a technological solution to a practical problem in the operation of the computer: it requires fewer computer operations to arrive at the optimised circuit than the prior art method, and in effect allows the computer to perform the optimisation more accurately and efficiently. The steps in the method relating to how the computer performs the analysis are therefore a statutory contribution, and the claim is consequently patentable.

Note that the question of *how* the hierarchical analysis and optimisation is performed is essential to the claimed invention; it is worth reiterating, in respect of this example in particular, that depending on the extent of the description and the state of the common general knowledge, specific details regarding the implementation of the method may be required in the claim.

Note that if the hierarchical approach had already been known, the analysis would be different. In that case, a contributed technological solution to a technological problem would only exist if a specific obstacle to implementing the steps relating to the hierarchical approach in a computer had been overcome. In such a case, the specific inventive operations to be performed by the computer to provide this solution would need to be specified.

Claim 2 is directed to a computer program *per se*, and is defective in form.

Claim 3, in contrast, illustrates a claim properly directed to a computer product. Given that the method of claim 1 is patentable, a computer implementing the entire method also would be patentable. The subject-matter of claim 3, a physical memory embodying a computer program that would render a computer running it patentable, is likewise patentable.

Example 2:

An application discloses a CAD program for optimizing transistor sizing for combinatorial networks. The program uses the Logical Effort gate delay model to optimize transistor sizing based on gate load and the desired delay characteristics. The program takes as inputs a schematic netlist file and the desired delay through the critical path of the circuit. The program calculates the optimum width and length for each transistor in the critical path of the circuit, and produces an output netlist file with that information.

The prior art search reveals that the following features are known from D1:

- The Logical Effort gate delay model and associated equations are known
- Using the Logical Effort gate delay model to optimize transistor sizing is known

The prior art does not disclose using a computer program to automatically optimize transistor sizing based on Logical Effort, taking as inputs only the netlist and the desired delay.

Claims:

> 1. A computer-implemented method for optimising the transistor sizing of a circuit schematic, comprising the steps of:
> - reading a netlist file defining all circuit elements and interconnections;
> - reading an input defining the desired delay of the critical path of the circuit;
> - identifying the critical path of the circuit;
> - identifying the fanout of each gate along the critical path;
> - calculating optimum transistor sizing for each gate along the critical path using the Logical Effort gate delay model, so as to provide the desired delay; and
> - generating an output netlist file having the optimum transistor sizing.

Analysis: Claim 1 defines a method for using a computer to optimise a circuit schematic. The claim is statutory in its form. The steps of reading a netlist file and generating an output netlist file can each be considered a discrete statutory element of the method, and it is understood that neither forms part of the contribution.

The remaining steps relate to a series of calculations. It is presumed for the purposes of this example that the description does not disclose any obstacles that were encountered in implementing the calculations on the computer. The sequence of operations necessary to perform the calculations would have been self-evident to a person skilled in the art presented with the equation. Consequently, there was no technological innovation in enabling the computer to perform the calculations. The steps of calculating are consequently simply the performing of an otherwise non-statutory method of calculation on a computer. Absent a technological problem to be overcome in how the computer performs the calculations, there is no statutory contribution in the claimed matter. Given that the specification emphasises the importance of the specific calculations, it would be appropriate to object to the claim under section 2 of the *Patent Act* in light of a contribution analysis.

16.09.05 Signals

The Office regards electromagnetic and acoustic signals and waveforms to be forms of energy and not to contain matter despite that the signal may be transmitted through a physical medium. As a result, claims to electromagnetic and acoustic signals do not constitute statutory subject-matter within the definition of *invention* in section 2 of the *Patent Act*.

More particularly, an electromagnetic or acoustic signal is interpreted to be neither an *art* nor a *process* because it is not an act or series of acts or method of operation by which a result or effect is produced by physical or chemical action. Neither is an electromagnetic or acoustic signal a *machine*, as it is not the mechanical embodiment of any function or mode of operation designed to accomplish a particular effect, or a *composition of matter*, as it is not a chemical compound, composition or substance. An electromagnetic or acoustic signal is considered not to be a material product and, therefore, not a *manufacture*.[13]

The Office considers signals to be transitory in nature, and to exist only while being propagated.[14] Once the information contained in a signal has been stored on a physical medium, it is no longer considered to be a signal and is more appropriately referred to as data. Therefore, claims that define a physical medium storing a signal or a waveform are considered indefinite under section 27(4) of the *Patent Act*.

Although signals *per se* are not patentable, methods, processes, machines or manufactures involved in the generation, transmission, reception, or processing of signals may be patentable if all other criteria for patentability are satisfied.

Example:

An application discloses a transmission system to transmit video data over short distances. The system uses a carrierless ultra wideband signal, where the video data is encoded into multi-phase wavelets. The system allows for transmission at high data rates over short distances, and can be used to transmit video from a security camera to a recording device, for example. When transmitted at low power, such carrierless transmissions do not interfere with narrowband or spread spectrum signals.

The prior art search reveals that the following features are known from D1:

- Wireless security system including security video cameras
- Wireless transmission of video data over short distances

D1 does not disclose the use of a carrierless ultra wideband signal where the data is encoded into multi-phase wavelets.

Claims:

1. A data signal for transmission of video data over short distances, the signal being embodied in a carrierless ultra wideband waveform wherein the data is encoded into multi-phase wavelets, the signal being transmitted from a transmitting antenna to a receiving antenna.

2. A physical transmission medium carrying the signal of claim 1.

3. A transceiver for transmitting and receiving data signals comprising:
- means for encoding video data into multi-phase wavelets;
- means for transmitting the encoded data as a data signal embodied in a carrierless ultra wideband waveform; and
- means for receiving and decoding the transmitted signal to retrieve the original video data.

Analysis: Claim 1 defines a signal *per se*, and is therefore directed to non-statutory subject-matter by its form and is objected to under section 2 of the *Patent Act*.

Claim 2 defines a physical transmission medium and is therefore directed in form to statutory subject-matter. The signal does not provide any technological limitation to the transmission medium, however, and the claim therefore includes two discrete elements (the medium and the signal). Since the physical transmission medium has self-evidently not been contributed, the claim does not include a statutory contribution. As the signal of claim 1 appears to be the inventive aspect, an objection is made under section 2 of the *Patent Act* in light of the contribution analysis.

Claim 3 defines, in form, a statutory device. The claim recites means for encoding, transmitting, and receiving and decoding data signals. For the purposes of this example, it is presumed that it is clear from the description that certain of the means relate to hardware components and others to software stored on a physical memory. The encoding of the data into multi-phase wavelets allows the transceiver to transmit data at a high rate while minimizing interference with other signals. Thus, the technological character of the device is modified by the software-enabled encoding. The claim does not include a discrete non-statutory element, and the patentability of the claim is evaluated on the basis of the novelty and ingenuity of all the defined elements in combination. Presuming the use of multi-phase wavelets is considered novel and inventive, the claim would be allowable.

Endnotes for chapter 16

1. Source code for computer programs may, however, be subject to the protection of the *Copyright Act* as a literary work.

2. *Schlumberger Canada Ltd. v. Commissioner of Patents* [(1981), 56 C.P.R. (2nd), 204 (F.C.A.)] at page 206

3. *i.e.* provide a technological solution to a technological problem

4. *Re Application for Patent Containing Claims that Read on Mental Steps* [(1972), 23 C.P.R. (2nd), 93] ; *Re Application 269,230 of Itek Corporation* (1981) C.D. 896

5. *Baker Petrolite Corp. v. Canwell Enviro-Industries Ltd.* [(2002), 17 C.P.R. (4th), 478 (F.C.A.)] at paragraphs [35] and [42]

6. *Bauer Hockey Corp. v. Easton Sports Canada Inc.* 2010 FC 361 at paragraphs [216] to [220]

7. *Bauer* (supra at 6) citing *Merrell Dow Pharmaceuticals Inc. v. H.N. Norton & Co. Ltd.* (1995), [1996] R.P.C. 76 (H.L.) at p. 86

8. *Bauer* (supra at 6) citing *Lux Traffic Controls Limited v. Pike Signals Limited*, [1993] R.P.C. 107 (Pat. Ct.) at p.132

9. *Baker Petrolite* (supra at 5) at paragraph [42]

10. *Baker Petrolite* (supra at 5) at paragraph [42]

11. see, e.g., the comments in *Re Application 2,349,479 of U-Haul International Inc.* (2010) C.D. 1298 at paragraphs [37] to [42]

12. *Re Application of U-Haul* (supra at 11) at paragraphs [37] to [42]

13. *Office Practice Regarding Signals* C.P.O.R. Vol. 135, No. 33, August 14, 2007

14. A signal is considered to be propagating even if it is moving in a closed loop.

Chapter 17
Biotechnology and Medicinal Inventions

17.01
Scope of this chapter – March 2016

This chapter provides guidance on Office practice particularly as it pertains to patent applications concerning inventions residing in the diverse field of "biotechnology", as well as "medicinal inventions".

The field of biotechnology can be thought of as encompassing "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use"..[1] Medicinal inventions, by their very nature, also interact with biological systems and encompass chemical compounds or compositions (and the preparation thereof) relating to or having therapeutic properties. It is important to note that although these descriptions offer a convenient means to label an invention, an invention may simultaneously exist in more than one field of technology.

In reading this chapter, it should be borne in mind that its purpose is to clarify, through elaboration, the application of the more generic teachings of other chapters to the examination of particular subject-matter common to biotechnology and medicinal inventions.

Nothing in this chapter should be interpreted as providing exceptions to any practice of general applicability set out in any other chapter.

17.02
Living matter – March 2016

The following subsections provide guidance for determining whether claims featuring living matter define statutory subject-matter within the scope of section 2 of the *Patent Act*. Section 2 requires the subject-matter of an invention to fall within one of the categories of invention, i.e., an art, process, machine, manufacture, composition of matter, or an improvement in one of the preceding categories [see Chapter 12 of this manual].

17.02.01
Higher and lower life forms – March 2016

For the purposes of section 2 of the *Patent Act*, life forms have in view of the jurisprudence[1] been divided into lower life forms (statutory) and higher life forms (non-statutory), with the distinction being, in general, whether the life form is unicellular (lower) or multicellular (higher).
Lower life forms are generally deemed to fall within the scope of section 2 as being either "manufactures" or "compositions of matter" since they can be produced *en masse* (bearing similarity to how chemical compounds are prepared) and formed in such large numbers that any measurable quantity will possess uniform properties and characteristics.[2]

Higher life forms do not fall within the scope of section 2 of the *Patent Act*.[3] Further, the Office takes the position that animals at any stage of development are not statutory subject-matter eligible for patent, and consequently fertilized eggs and totipotent stem cells[4] are included in the higher life form proscription.

A stem cell which is embryonic, multipotent or pluripotent[5] is not alone capable of developing into an animal and is considered to be a lower life form. Where a claim to a cell could be reasonably understood in view of the description as encompassing within its scope a fertilized egg or totipotent stem cell, this subject-matter should be expressly excluded by proviso, otherwise the claim may be construed as including matter excluded from the scope of section 2.

Note that the fact that a claimed cell could form part of a higher life form does not mean that the claim to the cell should necessarily be construed to be a claim to the higher life form. However, where, upon a purposive construction, a claim to a cell is construed to be a claim to a higher life form, the claim lacks compliance with section 2 of the *Patent Act*.

Where a claim is construed as an isolated cell, there is no need to specify in the claim that the cell is "as found in the laboratory" or is "in isolated form".[6]

Lower life forms include: microscopic algae; unicellular fungi (including moulds and yeasts); bacteria; protozoa; viruses; transformed cell lines; hybridomas; and embryonic, pluripotent and multipotent stem cells.

Higher life forms include: animals, plants, mushrooms, fertilized eggs and totipotent stem cells. Plant varieties that are distinct, uniform and stable may be protected under the *Plant Breeders' Rights Act*, administered by the Canadian Food Inspection Agency. A plant part such as a cutting, callus, rhizome, tuber, fruit, or seed (regardless of whether the seed is coated) is also considered to be a higher life form.

A claim that is not directed to a higher life form *per se* but instead includes a higher life form within its scope (e.g., as a component of a composition or food product, as a use, etc.) may, depending on the essential elements as determined through a purposive construction analysis, be statutory subject-matter. For example, consider a claim to "an animal feed comprising X". Where the claim is construed as the use of X for animal feed, the claim will likely be statutory regardless of whether X is a higher life form. When construed to be X or a product comprising X, the claim will be non-statutory if X is a higher life form. In cases where X is a higher life form that has been processed by significant chemical or physical modification, the claim may be construed as a manufacture within the definition of invention provided in section 2 of the *Patent Act*.

Note that a statutory method or process of producing a non-statutory higher life form will not change the determination that the life form itself is non-statutory.

Example 1:

In an application for patent, the inventors identify the problem to be solved as a need to provide a plant that is resistant to herbicide Q. The specification discloses a new recombinant plant and propagation material thereof produced by a process involving the transformation of a plant cell with an expression vector comprising a bacterial nucleic acid from *S. hygroscopicus* (SEQ ID NO:1) that confers resistance to herbicide Q.

Claims:

1. A plant transformed with an expression vector comprising the nucleic acid molecule depicted in SEQ ID NO:1.

2. A plant cell comprising the nucleic acid molecule depicted in SEQ ID NO:1.

3. The plant cell of claim 2, wherein the cell is in a plant.

4. A plant propagation material comprising the plant cell of claim 2.

5. A seed comprising the nucleic acid molecule depicted in SEQ ID NO:1.

6. An artificial seed comprising:

   a) embryonic plant tissue comprising the nucleic acid molecule depicted in SEQ ID NO:1; and

   b) an alginate layer that encapsulates the embryonic plant tissue.

7. A bacterial host cell transformed with an expression vector comprising the nucleic acid molecule depicted in SEQ ID NO:1.

Analysis: Claims 2 and 7 are each construed to be directed to statutory subject-matter within the scope of section 2 of the *Patent Act*. In contrast, the subject-matter defined by each of claims 1 and 3-6 is non-statutory because each claim is construed to be directed to a higher life form, which lies outside the definition of "invention" as defined in section 2 of the *Patent Act*. More specifically, claim 1 is construed to be directed to a plant and claims 4-6 are construed to include seeds. Although the preamble of claim 3 defines a cell, it is important to note that the claim specifies the cell is in a plant. Thus, the claim is construed to be directed to an entire plant.

Example 2:

An application describes a novel transgenic pig that produces odourless manure due to the introduction and expression of a transgene (SEQ ID NO:2) in its genome.

Claims:

1. A fertilized porcine ovum transfected with DNA having the sequence of SEQ ID NO:2.

2. A cell line consisting of cells transfected with DNA comprising the sequence of SEQ ID NO:2.

3. A transgenic pig comprising cells as defined in claim 2.

4. Use of the pig of claim 3 for producing odourless manure.

Analysis: Claims 1 and 3 are non-statutory. Claim 1 is construed as a fertilized ovum, which has the inherent ability to develop into an animal, while claim 3 is construed as a higher life form. Consequently, the subject-matter of both claims is non-statutory. In contrast, claims 2 and 4 are statutory. Claim 2 is construed as a composition of matter and claim 4 defines a statutory "art" when construed to be the use of the pig and not the pig itself.

17.02.02
Organs and tissues – March 2016

Organs and tissues (whether of plant or animal origin) are generally not considered to be manufactures or compositions of matter for the purposes of section 2 of the *Patent Act*. Organs and tissues are in general created by complex processes, elements of which require no human intervention, and do not consist of ingredients or substances that have been combined or mixed together. In view of this, the Office considers that a genetically-modified organ or tissue is not statutory subject-matter.

Artificial organ-like or tissue-like structures that are distinct from true tissues and organs and that have been generated by human intervention through the combination of various cellular and/or inert components may be considered, on a case-by-case basis, to be manufactures or compositions of matter within the scope of section 2 of the *Patent Act*.[7] For example, functional and anatomical differences may be indicators that serve to distinguish an organ-like or tissue-like structure from a true organ or tissue.

17.02.03
Processes to produce life forms – March 2016

The patentability of a method or process is independent of whether or not the product of the method or process is statutory. Processes to produce higher life forms, organs or tissues are not, therefore, defective on the grounds that they produce non-statutory products.

An especially important consideration is the degree of human intervention embodied in the claimed process. A process which occurs essentially according to nature, with no significant human intervention, is not patentable.[8] Thus, for example, a claim construed to be directed to a process for producing a plant solely by traditional cross-breeding techniques is not patentable (even where one of the cross-bred plants is transgenic or otherwise modified). A process that is a result of both human intervention and the laws of nature, however, is patent-eligible subject-matter where at least one step of human intervention is an essential element of the claim.

Processes that are considered to include significant human intervention include: processes to produce a lower life form, processes to produce a higher life form (if more than traditional breeding techniques), processes to produce an organ or a tissue through genetic transformation; processes for the *in vitro* culturing or manipulation of cells; processes to separate cells; and processes to generate mutants using a chemical or physical agent.

Example 1:

An application discloses a need for a new insect-resistant cotton plant. The description discloses a process for producing an insect-resistant transgenic plant, which requires the transformation of plant cells with a Bt toxin gene from a bacterium. Although transformation techniques were part of the common general knowledge of the person skilled in the art, it was not well known that insect resistance in cotton could be conferred by transforming plant cells with a Bt toxin gene.

Claims:

1. A process to produce an insect resistant cotton plant, comprising:

    a) transforming a plant cell with an expression vector carrying a nucleic acid sequence encoding a Bt toxin gene;

    b) generating a transgenic parent plant from said transformed cell;

    c) crossing the plant of step b) with a plant of cotton variety B;

    d) selecting progeny of said cross that have insect resistance; and

    e) backcrossing the selected progeny with the transgenic parent plant.

2. A transgenic plant produced by the process of claim 1.

Analysis: The problem to be solved by the invention is determined to be a need to produce a new insect-resistant cotton plant. In this case, the solution is a process that relies on the transformation of a plant cell with a Bt toxin gene to generate a transgenic plant, which is followed by steps of traditional breeding that ultimately produce an insect resistant plant. Given that steps a) through e) provide the identified solution, these steps are all considered essential elements of claim 1. Thus, claim 1 defines statutory subject-matter since step a), which involves significant human invention, is an essential element of the claim. The fact that the process yields a non-statutory product (a plant) has no effect on the patentability of the process.

It should be emphasized that a proper assessment for patentability must be based on a purposive construction of the claim and not simply on a literal interpretation of the claim. For example, consider a different scenario in which it was common general knowledge that insect-resistant cotton plants are produced by transforming plant cells with a Bt toxin gene. In this scenario, the inventor discovered that the existing process, which uses transgenic Bt toxin plants, could be improved by using cotton variety B in crossbreeding. Thus, given that the person skilled in the art would recognize that transforming a cotton plant with a Bt toxin gene represents a commonly known solution to a commonly known problem, the problem would instead be viewed as a need to improve the process for producing insect-resistant cotton plants. In this case, the solution is based on the use of variety B in the breeding process, as represented by steps c) to e) of the claim. Given that the essential elements of the claim are limited to steps of traditional breeding [steps c) to e)], the claim would not define a statutory invention as defined in section 2 of the *Patent Act*.

Claim 2 is non-statutory. The subject-matter of the claim defines a higher life form and no degree of human intervention in its production can change the determination that it falls outside the definition of invention in section 2 of the *Patent Act* [see 17.02.01].

Example 2:

The description discloses a need for biological systems that can be used to screen cancer therapeutics. The description discloses a novel and inventive process for producing a skin-equivalent that is useful for screening potential anti-melanoma drugs.

Claims:

1. A process for producing a skin-equivalent, comprising:

(i) providing a perforated biocompatible membrane;

(ii) seeding said membrane with epithelial cells; and

(iii) cultivating said cells thereon *in vitro*.

2. A skin-equivalent produced by the process of claim 1.

Analysis: Given that the process of claim 1 requires significant human intervention, and the end result of the process, the skin equivalent (claim 2), is functionally and anatomically distinct from natural skin [see 17.02.02], the subject-matter of these claims is not excluded from the scope of section 2 of the *Patent Act*. Therefore, the claims are statutory.

Example 3:

An application discloses a need for a sheep breed exhibiting the desirable trait of decreased wool fibre diameter and a need for an improved breeding method to produce such sheep. The inventors screened sheep for a genetic polymorphism and disclosed that a genetic marker (BAA81) on chromosome 11 correlated to the desired trait. Marker assisted selection was performed to identify sheep having the marker. In brief, DNA primers specific to the region surrounding the BAA81 marker were created, the primers were mixed with genomic DNA isolated from a sheep and PCR was performed. Sheep selected by this process were mated to produce progeny that exhibited significantly decreased fibre diameter compared to sheep lacking the marker.

Claim:

1. A method for producing sheep having decreased wool fibre diameter comprising:

a) performing a marker assisted selection by identifying molecular marker BAA81 in chromosome 11;

b) selecting a ram and ewe homozygous for BAA81; and

c) mating to produce sheep having decreased wool fibre diameter.

Analysis: It is clear that identification of the BAA81 region on chromosome 11 was not part of the common general knowledge. Recognizing that the problem to be solved was to produce sheep that have decreased wool fibre diameter, the inventors solved the problem using an improved breeding method that relied on marker assisted selection to identify the BAA81 polymorphism (step a) and selective breeding of only those sheep having the marker (steps b and c). Hence, in this case, all the steps of the claimed method are essential to solving the problem. The claim defines statutory subject-matter within the scope of section 2 of the *Patent Act* since the method relies on significant human intervention (step a) and is not construed as being limited to steps of traditional breeding.

17.02.04
Bioinformatics – January 2009

Biomolecules are chemical compounds, and claims to nucleic acids, polypeptides, proteins and peptides are therefore directed to statutory matter. Certain biomolecules, further, express information through their primary structure (i.e. their sequence).

The three-dimensional structure of a biomolecule is often of importance in understanding its biological activity and behavior. A claim to a biomolecule, defining the molecule in terms of its atomic coordinates, is statutory. In contrast, a claim to the three-dimensional atomic coordinates that represent the shape of the biomolecule in space is not statutory. The coordinates themselves are simply information, which is non-statutory.

Note that the exclusion from patentability of information does not depend on whether or not the information has been recorded on a carrier, nor on the nature of the carrier.

A computer model of a biomolecule which relies on the structural information of the biomolecule is not patentable, since the model itself equates to a graphical presentation of the underlying information. This exclusion extends to include generic computer systems and/or programs that have merely been configured to generate the model.

Computer models of biomolecules can be used in, for example, *in silico* screening methods. The mere presence of a computer model of a biomolecule in a method does not of itself render the method unpatentable.

Examples:

1. A polypeptide comprising the amino acid sequence depicted in SEQ ID NO: 1.
(statutory)

2. A protein comprising the atomic coordinates set out in figure 1.
(statutory)

3. A computer readable medium having recorded thereon the sequence set forth in SEQ ID NO: 1.
(non-statutory)

4. Atomic coordinates of protein X, said coordinates depicted in figure 1.
(non-statutory)

5. A method of obtaining inhibitors of protein X, comprising the steps of:

(i) generating a three-dimensional computer model of protein X using the atomic coordinates depicted in figure 1;

(ii) identifying the binding site of protein X using said model; and

(iii) electronically screening a library of compounds with defined spatial coordinates in order to identify compounds which are structurally complementary to the binding site of protein X; and

(iv) preparing complementary compounds as inhibitors of protein X.
(statutory)

17.03
Medical methods and uses – November 2017

17.03.01* (formerly 17.02.03a*)
Medical and surgical methods – January 2009

A method which provides a practical therapeutic benefit to a subject, even if this is not its primary or intended purpose, is considered to be a method of medical treatment and is therefore not patentable.[1] By way of examples, surgical, medical, dental and physiotherapeutic methods of treatment are non-statutory matter.

To be considered a method of medical treatment, the method should cure, prevent or ameliorate an ailment or pathological condition, or treat a physical abnormality or deformity such as by physiotherapy or surgery. Certain natural conditions such as ageing, pregnancy, baldness and wrinkles are not considered to be pathological, and methods to treat such conditions are therefore not proscribed.

Methods that involve performing surgery on the human or animal body are excluded, whether the effect of the surgery is therapeutic or not. Methods that involve the excision of tissue, organ, or tumour samples from the body are considered to be forms of surgery, and are excluded regardless of their reproducibility. The removal of fluids from the body such as by needle or cannula is not of itself surgery.[2] A method to remove fluids may nevertheless be proscribed if it otherwise involves surgery, such as in the placement of a cannula or stent in the body,[3] or if it lacks utility, e.g. for not being reproducible.

Claims which do not involve a step of surgery or provide a practical therapeutic benefit do not form part of the method of surgery or medical treatment exclusion.[4] Thus, certain methods of diagnosing a disease or medical condition, whether practised in vitro or in vivo,[5] of treating an animal solely to derive an economic benefit,[6] or for achieving a cosmetic result may be patentable.

As mentioned in subsection 11.10.02, use claims are permitted but are scrutinized closely to ensure they do not equate to a medical or surgical method, for example by the inclusion of a medical or surgical step.

Similarly, a claim which recites a dosage regime, or a prescribed dosage amount, may be directed to a method of medical treatment since dosage regimes and prescribed dosage amounts fall within the purview of a medical professional.[7] However, dosage forms, pharmaceutical packages or kits, which may physically embody a dosage regime or prescribed dosage amount, are considered patentable subject matter.[8]

The removal of the medical aspect of a claim may render it acceptable. Inclusion of terms such as "cosmetic", "diagnostic" or "non-medical" in a claim may be taken as disclaimers to medical methods provided the description contains adequate support for such terminology and provided the claim can reasonably be understood to be directed to a non-medical method the results of which cannot reasonably be said to produce a practical therapeutic effect.

Examples:

> 1. A method of preventing cervical cancer in a human subject, comprising administering a human papilloma virus peptide defined by SEQ ID NO: 1 to said subject.

Analysis: non-statutory, since the method is self-evidently a method of medical treatment.

> 2. A method of producing antibodies specific for the human papilloma virus peptide defined by SEQ ID NO: 1, comprising administering said peptide to a rodent.

Analysis: statutory, since rodents are not susceptible to human papilloma virus and do not derive any therapeutic benefit from the administration of the peptide.

> 3. A method of producing tenderized meat, comprising:
>
> (i) injecting an animal with a proteolytic composition; and
>
> (ii) slaughtering said animal after a period of time sufficient to allow for tenderization of the meat of said animal.

Analysis: statutory, since the animals do not obtain any therapeutic benefit from the method, and the method has clear industrial applicability.

> 4. A method for detecting and localizing a breast tumour, without medically treating said tumour, which method comprises the following steps:
>
> (i) injecting a subject with an antibody X which has been labelled with a diagnostically effective amount of a radioactive isotope;
>
> (ii) allowing said labelled antibody to localize at the site of the breast tumour; and
>
> (iii) detecting the emission of radioactivity from said radioactive isotope thereby localizing the site of the breast tumour in said subject.

Analysis: Statutory because, in this case, there is a distinction between the concentration of the radioisotope-labelled antibody which is used for diagnosis and that which would provide a therapeutic effect. The proviso "without medically treating said tumour" therefore qualifies the amount of antibody used and restricts it to non-therapeutic concentrations.[9]

> 5. A method of analyzing a sample of breast tissue to diagnose breast cancer in a subject, comprising the following steps:
>
> (i) homogenizing said sample in extraction buffer to yield soluble and insoluble fractions;
>
> (ii) separating the soluble fraction from the insoluble fraction;
>
> (iii) reacting the soluble fraction with [novel] antibody X; and
>
> (iv) detecting specific binding of antibody X with antigen Y
>
> wherein specific binding of antibody X to antigen Y indicates the presence of breast cancer.

Analysis: Statutory, since the method is clearly a diagnostic method and has been drafted in such a manner that any acts required to obtain the necessary sample of breast tissue do not form part of the claimed invention.

> 6. A method of detecting breast cancer in a subject comprising the following steps:
>
> (i) obtaining a sample of breast tissue from a subject by [novel] needle biopsy conducted under the virtual guidance of a system which generates a three-dimensional image of a putative breast tumour which has been localized in vivo by immuno-radiography with an antibody reactive with antigen Y; and
>
> (ii) detecting the presence of antigen Y in said sample,
>
> wherein the presence of antigen Y at an amount exceeding 125 ng/g of tissue

indicates the presence of breast cancer.

Analysis: non-statutory, since step (i) involves a step (a needle biopsy) which equates to surgery.

7. A method of screening for a potential drug for [human] disease X, comprising:

(i) administering a plurality of test compounds to [novel] mice which have been genetically engineered by insertion of human gene Y to mimic disease X;

(ii) evaluating the severity of disease progression in said mice in the presence and absence of each of the compounds; and

(iii) selecting compounds which slow disease progression as potentials for treating disease X.

Analysis: statutory, since a method wherein a disease is induced in an otherwise healthy subject is not a method of medical treatment, even if the so-induced disease is subsequently treated.

17.03.02
This section has been left intentionally blank

17.03.03
Kits and packages – November 2017

This section focuses on the patentability of claims to kits and packages in the context of medical inventions.

A "package" is generally understood as one or more components that are contained within conventional packaging material, such as a box, paper or plastic wrapping, or the like. The person skilled in the art would understand that a package may contain a single component, a plurality of the same component, one or more different components, or any combination of these without limitation. Where appropriate, a package may be defined more particularly as, for example, a commercial package or a pharmaceutical package.

A “kit” is generally understood as a specific type of package that contains two or more components.

When a kit contains a composition, such as a unit dosage form, which is composed of two or more ingredients that are formulated together, that single formulated product is considered as one component in the kit. Thus, one unit dose would not reasonably be considered as two separate components in a kit. The skilled person would understand that there is a difference between a “composition” and a “kit”, based on the plain and ordinary meaning of those terms.

When a pharmaceutical composition comprising an active ingredient is a component in a medical kit, the following is a non-exhaustive list of examples of what the second component may be: an instrument for administration, e.g., an applicator, empty syringe or graduated cup; a separate formulating excipient, adjuvant or potentiator; a separate activating agent, reagent, or buffer; an antiseptic wipe; a test strip; a separate product comprising a second active ingredient; or instructions defining the use. See 17.03.03*b* below for a more detailed discussion of instructions.

17.03.03*a*
Claims of indefinite scope or lacking clarity

The subject-matter of a claim must be defined distinctly and in explicit terms, in accordance with subsection 27(4) of the *Patent Act*, because the claims define the subject-matter of the monopoly. The scope of a claim must be clear and definite from the perspective of the person skilled in the art.

The terms “package” and “kit” are used interchangeably at times. In some cases this leads to a lack of clarity or creates avoidable ambiguity within a claim or set of claims, contrary to subsection 27(4) of the *Patent Act*.

A kit would be understood as a specific type of package comprising at least two components so, in order to comply with subsection 27(4) of the *Patent Act*, the term “kit” must be construed as having a minimum of two components. Where the term “kit” is construed as consisting of only one component, the claim to the kit would not comply with subsection 27(4) of the *Patent Act*. For instance, a subsection 27(4) defect would be identified where the application defines a kit as **consisting of** only one component. A subsection 27(4) defect may also be identified in cases where the application states that a kit is an embodiment of the invention but does not explicitly describe the components of said kit **and** the examiner construes the kit as having only one component. In contrast, no defect would be identified in cases where either the description or claim unambiguously defines the kit as containing at least two components or where the examiner construes the kit as containing at least two components.

If a package claim defines two or more components then there would be no lack of clarity even though the subject-matter could have been claimed as a kit. There are no restrictions on the number of components a package may contain.

A patent application may contain multiple independent product claims within the same claim set, such as claims to a package, a kit, and a package containing the kit, as long as the existence of the multiple product claims does not result in a lack of clarity.

Example

An application discloses that compound A, a known herbicide, has therapeutic utility for treating disease Y in humans. The description states that compositions comprising compound A may be formulated for a variety of routes of administration, but focuses on subcutaneous and intravenous injectable formulations and liquid oral formulations. In one embodiment the formulation and an empty syringe may be packaged together within a kit. The description also discloses using the formulation in combination with a second compound that also treats disease Y, and refers to a number of compounds well known for treating Y. Also described is an embodiment where compound A is packaged together with a second compound for treating disease Y.

Claims:

1. A pharmaceutical composition comprising compound A and a pharmaceutically acceptable formulating excipient.

2. A kit comprising the pharmaceutical composition of claim 1.

3. The kit according to claim 2, further comprising an instrument for administering the pharmaceutical composition.

4. A package comprising the kit of claim 2.

Analysis: Claim 1 complies with subsection 27(4) of the *Patent Act*. The claim is directed to a pharmaceutical composition comprising at least two ingredients, namely compound A and a pharmaceutically acceptable formulating excipient. The excipient is defined in broad terms but the nature and scope of the excipient would be clear to the skilled person based on their common general knowledge and in view of the specification as a whole, based on the terms "pharmaceutically acceptable" and "formulating".

Claim 2 complies with subsection 27(4) of the *Patent Act*. The claim is directed to a kit comprising the pharmaceutical composition of claim 1. The claim only explicitly defines one component of the kit, namely the composition, and there are no indications in the claim relating to the nature of a second component. However, given that there is a basis in the description for what the second component of the kit may be, e.g. a syringe or the additional compound for treating disease Y, the scope of the claim would be understood as comprising at least two components and, therefore, satisfies subsection 27(4) of the *Patent Act*.

Claim 3 complies with subsection 27(4) of the *Patent Act*. The claim is directed to a kit comprising the pharmaceutical composition of claim 1 and an instrument for administering the composition. The instrument is defined in broad terms, but the nature and scope would be clear to the skilled person, based on their common general knowledge and in view of the specification as a whole. Notably, the claim would have also complied with subsection 27(4) if the second component of the kit was defined as the additional compound for treating disease Y.

Claim 4 complies with subsection 27(4) of the *Patent Act*. The claim is directed to a package comprising the kit of claim 2. As discussed above for claim 2, the kit satisfies subsection 27(4). In this case, the placement of the kit within a package does not lead to a lack of clarity and, therefore, the subject-matter of claim 4 also satisfies subsection 27(4) of the *Patent Act*. Notably, claim 4 would also be compliant with subsection 27(4) if it referred to claim 3 instead of claim 2.

Note that the claims must still be assessed for compliance with the other requirements of patentability.

17.03.03*b*
Instructions

Instructions are generally understood as information printed or displayed on a substrate. In the context of medical inventions, this information often suggests actions or directions that can be taken, such as how an active agent can be administered or used in treatment.

Instructions may be claimed as a secondary component of a kit or package; however, there is no general requirement that a kit or package comprise instructions.

Where a use is defined in the preamble or body of a claim or as part of the instructions, the claim may be construed as a "kit for use" or "package for use", which is distinct from a claim to a kit or package per se. For instance, claims such as "a kit comprising A and B and *instructions for using A and B to treat disease Y*" and "a kit *for treating disease Y* comprising A and B" are both construed as "kit for use" claims.

Example

An application discloses there is a need for improved treatment of painful diabetic neuropathy in patients. The description states that the inventors have surprisingly discovered that levetiracetam and carbamazepine (known anti-epileptic drugs), when used in combination, are effective for reducing pain associated with diabetic neuropathy.

Claims:

1. A kit comprising:
a) a first pharmaceutical formulation comprising levetiracetam; and
b) a second pharmaceutical formulation comprising carbamazepine.

2. The kit of claim 1 further comprising instructions for using levetiracetam and carbamazepine to treat pain associated with diabetic neuropathy.

A search of the prior art identified patent document D1, which discloses the combined use of levetiracetam and carbamazepine in epileptic patients. An embodiment of D1 includes a kit comprising both levetiracetam and carbamazepine as well as instructions for preventing seizures in patients.

Analysis: Claims 1 and 2 comply with subsection 27(4) of the *Patent Act*. Claim 1 recites a kit comprising a first pharmaceutical formulation comprising levetiracetam and a second pharmaceutical formulation comprising carbamazepine. The scope of claim 1 would be understood as a kit containing at least two components, namely the first and second pharmaceutical formulations. In claim 2, the skilled person would understand that the instructions, which define the use of levetiracetam and carbamazepine, represent an additional component of the kit. In view of this, the claims satisfy subsection 27(4) of the *Patent Act*.

In regard to the requirement for novelty, claim 1 is anticipated by D1 because D1 discloses and enables a kit comprising both levetiracetam and carbamazepine. Recognizing that the kit of claim 2 further comprises instructions for using levetiracetam and carbamazepine to treat pain associated with diabetic neuropathy and that D1 does not disclose and enable this use, claim 2 is novel over D1. Thus claim 2 is regarded as a new use of a kit comprising levetiracetam and carbamazepine that complies with section 28.2 of the *Patent Act*.

Note that the claims must still be assessed for compliance with the other requirements of patentability.

17.03.04
Medical diagnostic methods – November 2017

The examination of patent applications featuring medical diagnostic method claims presents certain challenges and warrants specific guidance to ensure efficient, predictable, and reproducible examination.

A diagnostic method outlines a sequence of steps to be followed to extract diagnostic meaning from data and will often comprise steps to:

- acquire data about an analyte.[10] (e.g., identifying, detecting, measuring, etc. the presence or quantity of X in a sample); and
- analyze the significance of the acquired data (e.g., wherein the presence, increase/decrease of the quantity, etc. of X correlates to condition Y).

In order to determine the patentability of a diagnostic method claim, the examiner must take into account the general guidance on purposive construction in Chapter 13 of this manual, which involves a determination of the problem addressed by the application, the solution as contemplated by the inventor and the essential elements that provide the solution. It follows that an evaluation for compliance with section 2 of the *Patent Act* is to be made on the basis of the essential elements as determined through a purposive construction.

The guidance herein may be applicable to claims in a form such as:

- A method of diagnosing disease Y by detecting analyte X, wherein the presence of X indicates that a patient has disease Y;
- A method of predicting the prognosis of a subject having disease Y comprising determining the expression level of analyte X, wherein increased expression correlates to a good survival probability;
- A method of determining if a patient will respond to treatment by measuring analyte X, wherein the patient will respond to treatment if X is below threshold value...;
- Use of a method to diagnose disease Y, characterized in that a sample is examined for the presence of analyte X;
- Use of analyte X to diagnose disease Y;
- A kit for diagnosing disease Y comprising components A and B...;
- Use of a device for determining whether a patient has disease Y, the device comprising a microarray having two or more oligonucleotides selected from A, B, C, D, E, F,... and P;
- Use of a compound to treat a patient suffering from disease Y wherein the presence of analyte X, which indicates that the patient has disease Y, was determined;
- a computer-implemented method for diagnosing disease Y; or
- any claim having similar language when construed to be a claim to a diagnostic method *per se*.

17.03.04*a*
Identifying the problem

The identification of the problem and the solution provided by the invention informs the purposive construction of the claims..[11] An identification of the problem is guided by the description and the examiner's understanding of the common general knowledge in the relevant art.

Examiners should bear in mind that an application may describe more than one problem to be solved. For diagnostic methods, it may be appropriate to consider that an inventor is generally looking to solve a **data acquisition problem** and/or a **data analysis**

problem.

Where a **data acquisition problem** exists, the description will typically describe technical matter that goes beyond the common general knowledge (CGK) of the skilled person in the art. Factors in the description that may indicate the existence of a **data acquisition problem** include:

- disclosure of a novel or non-CGK analyte;
- disclosure of a novel or non-CGK combination of biomarkers;
- disclosure of a novel or non-CGK means to identify or quantify an analyte (regardless of whether the analyte itself was known or CGK);
- disclosure that a CGK means to identify or quantify an analyte is applied to a sample or subject population that is not standard to that means;.[12]
- disclosure that a CGK means to identify or quantify an analyte is performed within specific constraints (e.g., timing) that is not standard to that means;.[13]
- explicit statements that a specific problem or solution relates to how to identify or quantify a particular analyte;
- a significant level of detail devoted to describing the technical details of how data about a particular analyte is acquired; and/or
- an emphasis on the challenges or deficiencies of prior means to identify or quantify a particular analyte.

Factors in the description that may suggest that a **data analysis problem** exists include:

- explicit statements suggesting the problem to be solved is a **data analysis problem** or something other than a **data acquisition problem**;
- placing an emphasis on the discovery of an allegedly new correlation between a condition and an analyte that is CGK with a relative absence of technical details pertaining to how to acquire the data about the analyte;
- indicators or explicit statements that, in order to acquire data about a particular analyte, it is CGK to apply the means contemplated by the application; and/or
- an absence of any explicit indication in the application that any practical problems were overcome relating to how to acquire data about an analyte that is CGK.

Once the problem is identified, the examiner must determine the solution to the problem as contemplated by the inventor. In some cases, the problem may not be readily apparent and an identification of the solution may actually inform the problem addressed by the invention.

17.03.04*b*
Determining the solution to the identified problem

Recall from Chapter 13 that the solution is the element or set of elements that is essential to the successful resolution of the problem. If a claim includes solutions to more than one problem, examination should focus on one solution to a problem in performing the purposive construction. The initial choice of solution should be guided by the description, selecting the solution given the greatest emphasis by the inventors. If it becomes necessary to consider a different solution, the analysis should be undertaken anew.

Where a **data acquisition problem** has been identified, the solution is provided by those elements that provide a means to acquire data about an analyte. The means by which the data is acquired may be represented by either a single step or by multiple steps within the diagnostic claim.

For example, elements relating to **data acquisition** may be represented by steps such as:

- detecting protein X in a subject sample;
- measuring the concentration of substrate X;
- determining the expression levels of genes A, B and C;
- contacting a urine sample with antibody A and determining the optical density at 450 nm; or
- incubating a sample with a nucleic acid probe consisting of SEQ ID NO:1 and detecting hybridization between the probe and target sequence Z.

Where a **data analysis problem** has been identified, the solution is provided by those elements that relate to the analysis of acquired data for the purpose of providing diagnostic meaning.

For example, elements relating to **data analysis** may be represented by steps such as:

- relating the presence of protein X from said test sample to a diagnosis of whether the test sample is from a subject suffering from disease Y;

- comparing the expression levels of genes A, B and C to a control standard, wherein a decrease in the levels as compared to the control is indicative of disease Y;
- wherein if the sample has a value greater than 0.24 then disease Y is suspected; or
- wherein hybridization of the probe to a target is indicative of the presence of disease Y.

17.03.04*c*
Purposive construction

Having identified the problem and solution, a purposive construction of the claims involves:

- interpreting the meaning of the various terms used therein; and
- determining whether elements in the claims are essential (provide the solution to the identified problem) or non-essential (do not provide the solution to the identified problem).

Recognizing that how data is analyzed or interpreted in a diagnostic method generally has no material effect on how the data needs to be physically acquired (and *vice versa*), the **data acquisition** elements and **data analysis** elements in the diagnostic method claim likely have a relationship reflecting an aggregation rather than a combination. Thus, the solution to a problem will be provided by either **data acquisition** elements or **data analysis** elements, but not both.

Where a **data acquisition problem** exists, the essential element or set of essential elements providing the solution is the means to acquire data about an analyte. If the identified problem does not relate to data acquisition then it will presumably relate instead to a **data analysis problem**. Where this is the case, the essential elements will include steps relating to the mental analysis and/or intellectual significance of the data and will likely not include any steps to acquire the data since the way the data is acquired does not change the nature of the solution (e.g., how X is detected or measured in a sample will not change the intellectual significance of its presence).

17.03.04*d*
Determining whether a claim defines statutory subject-matter

A diagnostic claim construed as being limited to essential elements that are disembodied (e.g., mental process, lacking physicality, no practical application, etc.) will be identified as defective for not complying with section 2 of the *Patent Act* because the subject-matter does not fall within a category of invention as defined in section 2. This would generally apply to situations where the identified solution is only provided by an element or set of elements associated with the analysis or significance of the acquired data (e.g., correlation of a marker to a disease).

By contrast, **data acquisition** elements likely define statutory subject-matter since they usually relate to tangible (non-disembodied) practical steps which fall within a category of invention as defined in section 2. Thus, where such a **data acquisition** element is identified as an essential element of the construed claim, the claimed subject-matter will likely be statutory unless the claim includes excluded subject-matter, such as a method of medical treatment.

17.03.04e
Examples

Example 1:

The following background information is applicable to all scenarios within Example 1. Each scenario will provide separate additional information about the prior art and/or CGK.

The specification describes a method of diagnosing whether a patient is at risk for developing thyroid cancer.

- The description states there is a need to identify a biomarker associated with thyroid cancer.
- It is disclosed that the presence of mutation A, corresponding to the presence of nucleotide A at position 123 of gene XYZ, correlates to a thyroid cancer risk.
- The steps required to identify mutation A in a biological sample are detailed in the description.
- Human gene XYZ was well known in the prior art as an important signalling pathway gene and the full-length of its nucleotide sequence was available in public gene databases prior to the claim date.
- The prior art does not disclose a correlation between gene XYZ and thyroid cancer.

Claim:

1. A method of diagnosing whether a human subject is at risk for developing thyroid cancer comprising:
    a) providing a biological sample from the subject;
    b) analysing the sample of step a) to determine the identity of the nucleotide at position 123 of gene XYZ; and
    c) wherein the subject is at risk for thyroid cancer if the identity of the nucleotide at position 123 is nucleotide A.

Scenario 1A:

- A mutation at position 123 within gene XYZ
    - was not CGK, and
    - was not specifically identified in any of the prior art.

Analysis:

Person of ordinary skill in the art (POSITA)

The POSITA is a team including an oncologist, an endocrinologist, a geneticist, a molecular biologist and a medical technologist.

Common general knowledge (CGK)

The CGK of the POSITA included knowledge of cancer treatment and diagnosis as well as conventional genotyping techniques. At the claim date, gene XYZ was a well-known signaling pathway gene and the gene, as well as data available in public databases about the gene, were CGK to the POSITA. In this scenario, mutation A in gene XYZ was not CGK to the POSITA.

The Problem

It is clear from the description and CGK that there is more than one problem to be solved by this invention. Given that the application discloses a need to identify a biomarker that correlates to thyroid cancer risk, this is suggestive that a data analysis problem exists. The description also makes apparent that the inventors are proposing a solution to a data acquisition problem since a mutation at position 123 of gene XYZ was not CGK to the POSITA and, by extension, methods of detecting and specifically acquiring data about the nucleotide at position 123 were also not CGK. Recognizing that means for specifically detecting the nucleotide at position 123 of gene XYZ were not CGK and that the description details how this is detected, a purposive construction will be based on the **data acquisition problem**: a need to detect and identify the nucleotide at position 123 of gene XYZ in a human subject.

The Solution

The identified data acquisition problem is solved by the provision of a method that, when practised:
1) provides means for detecting the identity of the nucleotide at position 123 of gene XYZ within a biological sample, and
2) specifically acquires data about the identity of the nucleotide at position 123.

What are the essential elements?

As the solution to the data acquisition problem is provided by steps (a) and (b) of the claimed method, these steps are essential elements of claim 1.

Statutory subject-matter – section 2

Claim 1, as construed, is statutory because the essential elements of the claim define subject-matter that falls within a category of invention as defined in section 2 of the Act.

Novelty – subsection 28.2(1)

Although the full nucleotide sequence of gene XYZ was known in the prior art, the prior art did not specifically disclose means to detect the nucleotide at position 123 in known gene XYZ in a biological sample from a human subject **and** specifically acquire data about the identity of the nucleotide at position 123. Therefore, the claim is novel because there is no single prior art disclosure that discloses and enables the essential elements of the claim.

Obviousness – section 28.3

Based on a reading of the specification as a whole from the perspective of the POSITA, in light of their CGK, the inventive concept of the claim includes a method that provides both a means for detecting the identity of the nucleotide at position 123 of gene XYZ within a biological sample, and the specific acquisition of data about the identity of the nucleotide at that position. Considering the prior art, it is apparent that genotyping techniques were well known at the claim date and the full length nucleotide sequence of gene XYZ (including position 123) was available to the POSITA from public databases. However, the difference between the prior art and the inventive concept is that the prior art did not disclose looking specifically at position 123 of gene XYZ in order to acquire data about the identity of the nucleotide at that position. The difference does not constitute a step that would have been obvious to the POSITA. Therefore, the construed claim is inventive.

Regarding claim 1 in scenario 1A:

Statutory subject-matter s2	Y
Novel 28.2(1)	Y
Non-obvious 28.3	Y

As the claim meets all of the requirements of patentability the claim is allowable.

Scenario 1B:

- **D1** discloses that nucleotide position 123 of gene XYZ has been determined to be a mutational hotspot across a population of tumour samples. Methods used to specifically identify a mutation at this position are also described. This information was not CGK to the POSITA.

Analysis:

Since neither the description nor the CGK have changed relative to *Scenario 1A*, the POSITA, CGK, problem, solution and essential elements remain as they were stated in that scenario. The analysis below takes into consideration the disclosure of prior art document **D1**.

Statutory subject-matter – section 2

Claim 1, as construed, is statutory because the essential elements of the claim define subject-matter that falls within a category of invention as defined in section 2 of the Act.

Novelty – subsection 28.2(1)

The claim lacks novelty in view of **D1** because **D1** discloses and enables the essential elements of claim 1, namely means for the identification of the nucleotide at position 123 of gene XYZ in a biological sample **and** the acquisition of specific data about the identity of the nucleotide at that position. It should be noted that, in this case, the actual identity of the nucleotide at position 123 (e.g., whether it is A, T, C or G) is not part of the claim or the essential elements.

Further, although **D1** did not disclose that a mutation at said position correlates to thyroid cancer risk, the claim is anticipated because this correlation is not an essential element of the data acquisition problem.

Obviousness – section 28.3

The claim is obvious in view of **D1** because it was already determined that the claim is anticipated by **D1** (see MOPOP 15.02.02*d*). For the sake of completeness, the examiner determines that the inventive concept of the claim includes a method that provides both a means for identifying the nucleotide at position 123 of gene XYZ within a biological sample, and the specific acquisition of data about the identity of the nucleotide at that position. **D1** discloses means for identifying the nucleotide at position 123 of gene XYZ in a biological sample **and** acquiring specific data about the identity of the nucleotide at that position. It is evident that there is no difference between the inventive concept of the claim and **D1** and, therefore, the POSITA would not have required any degree of invention to arrive at the inventive concept.

It should be noted that the data analysis elements do not form part of the inventive concept as the examiner has determined that a data acquisition problem was solved.

Regarding claim 1 in scenario 1B:

Statutory subject-matter s2	Y
Novel 28.2(1)	**N**
Non-obvious 28.3	**N**

The claim is not allowable as it does not meet all of the requirements of patentability

Scenario 1C:

- Each of **D2-D8** independently discloses testing human subjects for prostate cancer by determining the identity of the nucleotide at position 123 and looking at whether mutation A exists at that position. The examiner has determined that both the means for determining the identity of the nucleotide at position 123 in a biological sample from a human subject and the link between mutation A and prostate cancer were CGK.

Analysis:

Person of ordinary skill in the art (POSITA)

The POSITA is a team including an oncologist, an endocrinologist, a geneticist, a molecular biologist and a medical technologist.

Common general knowledge (CGK)

The CGK of the POSITA included knowledge of cancer treatment and diagnosis as well as conventional genotyping techniques. At the claim date, gene XYZ was a well known signaling pathway gene and the gene, as well as data available in public databases about the gene, were CGK to the POSITA. In this scenario, both mutation A in gene XYZ and the means of determining whether this mutation was present in gene XYZ at nucleotide position 123 in a sample were CGK to the POSITA (see **D2-D8**). Further, the link between mutation A at position 123 and prostate cancer was CGK.

The Problem

Considering the specification as a whole and the background of the CGK in the relevant field, the examiner has determined that a problem related to **data analysis** exists. More particularly, the problem appears to be related to a need to correlate a particular genotype in a human subject with a risk of developing thyroid cancer. Although the specification also describes methods for acquiring data about the mutation at nucleotide position 123 of gene XYZ, it is apparent that the inventors are not proposing a solution to a data acquisition problem of how to determine the sequence at position 123 of gene XYZ because its solution already existed in the CGK (see **D2-D8**).

The Solution

The solution to the identified data analysis problem was arrived at by the discovery of a correlation between the presence of a mutation at position 123 of gene XYZ and thyroid cancer.

What are the essential elements?

As the solution to the data analysis problem is represented by step (c) of the claimed method, the essential element of the claim relates to the correlation between mutation A at position 123 and the risk of thyroid cancer.

Statutory subject-matter – section 2

Claim 1, as construed, is not statutory because the essential element of the claim defines subject-matter that is disembodied and does not fall within a category of invention as defined in section 2 of the Act.

Novelty – subsection 28.2(1)

The claim is novel because there is no single prior art disclosure that discloses and enables the essential element of the claim, namely the correlation between mutation A at position 123 and the risk of thyroid cancer.

It should be noted that although each of **D2-D8** independently discloses and enables a method for identifying the nucleotide at position 123 of gene XYZ in a biological sample, the claim is not anticipated by any of **D2-D8** because the data acquisition steps in the claim that correspond to the means of detection are not essential elements of the data analysis problem.

Obviousness – section 28.3

Based on a reading of the specification as a whole from the perspective of the POSITA, in light of their CGK, the inventive concept of the claim is the correlation between the presence of mutation A at position 123 of gene XYZ and thyroid cancer. Taking into consideration the information disclosed in **D2-D8** and the CGK, it is apparent that mutation A at position 123 of gene XYZ was associated with prostate cancer. However, the prior art does not disclose an association with thyroid cancer. The examiner has concluded, in this case, that the POSITA would not have considered the association between mutation A at position 123 of gene XYZ and thyroid cancer to have been obvious at the claim date. Therefore, the construed claim is inventive.

Regarding claim 1 in scenario 1C:

Statutory subject-matter s2	**N**
Novel 28.2(1)	Y
Non-obvious 28.3	Y

The claim is not allowable as it does not meet all of the requirements of patentability.

It should be noted that if the applicant argues that a data acquisition problem (not a data analysis problem) was solved by their invention, the examiner would provide an alternative data acquisition problem analysis in a subsequent report.

Example 2:

The specification describes an improved method for diagnosing disease P, which is a lysosomal storage disease.

- The background of the invention discloses that methods for diagnosing disease P were well known in the art and involved measuring enzyme E activity within cultured skin samples wherein the patient is diagnosed as having disease P when the activity of enzyme E is lower than the control.
- According to the description, the diagnostic method of the invention is an improvement over existing methods of diagnosing disease P because enzyme E activity is measured from dried blood samples. The method is advantageous since it is less invasive and faster than methods of the prior art.
- The description details the steps of the improved method.
- **D1** discloses a method of diagnosing disease P which involves measuring enzyme E activity in cultured skin cells from patients.
- **D2** discloses a method of measuring enzyme activities in three lysosomal storage diseases related to disease P (but not including disease P) using tandem mass spectrometry on samples of dried blood obtained from patients. **D2** states that it is advantageous to carry out the determination of enzyme activity on dried blood samples rather than on conventional skin cell samples.
- The prior art does not disclose enzyme E activity measurement on blood samples.

Claim:

1. A method of diagnosing disease P in a subject comprising:
(a) providing a dried blood sample from said subject;
(b) measuring the activity of enzyme E in the sample, wherein enzyme E activity is detected by mass spectrometry; and

(c) diagnosing the subject as having disease P when the activity of enzyme E is lower than the activity of enzyme E in a control sample representative of normal subjects.

Analysis:

Person of ordinary skill in the art (POSITA)

The POSITA is a team including a medical practitioner, a biochemist, and a medical technologist.

Common general knowledge (CGK)

The CGK of the POSITA included knowledge of disease P and other lysosomal storage diseases, as well as existing biochemical assays for diagnosing such diseases. In this example, it was CGK to diagnose disease P by carrying out enzyme assays on skin samples. It was not CGK to measure enzyme E activity in blood samples.

The Problem

Considering the specification as a whole and the background of the CGK of the POSITA in the relevant field, the examiner has determined that the problem relates to **data acquisition**. Specifically, the identified problem is a need for an improved method of measuring enzyme E activity in a biological sample from a human subject. This conclusion was based on the fact that the instant description details an improved assay method dependent on sample selection which represents a solution that did not exist in the CGK prior to the invention.

The Solution

The identified data acquisition problem is solved by the provision of an improved method that, when practised:

1) provides means for measuring enzyme E activity by carrying out the measurement by mass spectrometry using a sample of dried blood; and
2) specifically acquires data about enzyme E activity.

What are the essential elements?

As the solution to the data acquisition problem is provided by steps (a) and (b) of the claimed method, these steps are essential elements of claim 1.

Statutory subject-matter – section 2

Claim 1, as construed, is statutory because the essential elements of the claim define subject-matter that falls within a category of invention as defined in section 2 of the Act.

Novelty – subsection 28.2(1)

The claim is novel because there is no single prior art disclosure that discloses and enables the essential elements of the claim.

Obviousness – section 28.3

Based on a reading of the specification as a whole from the perspective of the POSITA, in light of their CGK, the inventive concept of the claim includes an improved method which includes steps for measuring enzyme E activity by carrying out the measurement by mass spectrometry on a sample of dried blood and specifically acquiring data about the activity of enzyme E. With respect to the prior art, **D1** is considered the closest prior art and discloses a method of measuring enzyme E activity. The method of claim 1 differs from **D1** in that **D1** discloses that the enzyme assay was carried out on cultured skin cells while the instant method uses dried blood samples. This difference, however, does not amount to an inventive step in view of **D2**. The POSITA would have come directly and without difficulty to measure enzyme E activity in dried blood samples using mass spectrometry given that **D2** disclosed that the use of such samples exhibited an advantage over the use of cultured skin cells in assays for other enzymes implicated in related lysosomal storage diseases. Therefore, the claim is obvious in view of a **D1** when combined with **D2**.

Regarding claim 1 in Example 2:

Statutory subject-matter s2	Y
Novel 28.2(1)	Y
Non-obvious 28.3	**N**

The claim is not allowable as it does not meet all of the requirements of patentability.

Example 3:

The specification describes a method of diagnosing gastrointestinal infections based on the presence of combinations of markers in stool samples.

- According to the description, there is a need for a new diagnostic test for gastrointestinal infections.
- The description details the steps of the detection method and discloses that the presence of two of more protein markers selected from G, U, T and S in stool samples are indicative of the presence of pathogenic bacteria that correlate to gastrointestinal infections.
- **D1** discloses that each of protein markers G and U are uniquely associated with bacterial strain, X1. Each marker was separately identified in stool samples from human subjects. There is no evidence in **D1** that G and U were looked for in combination within the same sample. Further, the link between the combination of G and U and bacterial strain X1 was not CGK to the POSITA.

Claim:

1. A method of screening for pathogenic bacteria comprising:
(a) providing a stool sample from a subject;
(b) detecting a combination of two or more protein markers in the sample selected from G, U, T and S; and
(c) wherein the presence of the two or more markers in the sample indicates that the subject is likely to have a gastrointestinal infection.

Person of ordinary skill in the art (POSITA)

The POSITA is a team including a medical practitioner, a microbiologist, and a medical technologist.

Common general knowledge (CGK)

The CGK of the POSITA included knowledge of gastrointestinal infections and associated pathogenic bacteria. Means for detecting two or more of markers selected from G, U, T and S together in a stool sample were not CGK to the POSITA.

The Problem

Considering the specification as a whole and the background of the CGK of the POSITA in the relevant field, the examiner has determined that the problem relates to **data acquisition**. Specifically, the identified problem relates to the detection of combinations of two or more of markers G, U, T and S in a sample.

The Solution

The identified data acquisition problem is solved by the provision of a method that provides means for detecting combinations of two or more markers selected from G, U, T and S within the same stool sample; and that specifically acquires data about the presence of these markers.

What are the essential elements?

As the solution to the data acquisition problem is provided by steps (a) and (b) of the claimed method, these steps are essential elements of claim 1.

Statutory subject-matter – section 2

Claim 1, as construed, is statutory because the essential elements of the claim define subject-matter that falls within a category of invention as defined in section 2 of the Act.

Novelty – subsection 28.2(1)

The claim is novel. **D1** does not anticipate the construed claim because it does not disclose the detection of a combination of two or more of markers within the same stool sample.

Obviousness – section 28.3

Based on a reading of the specification as a whole from the perspective of the POSITA, in light of their CGK, the inventive concept of the claim is a method that provides means for detecting combinations of two or more markers selected from G, U, T and S within the same stool sample and specifically acquiring data about their presence in the sample. **D1** represents the closest prior art and discloses the specific association of each of markers G and U with bacterial strain X1, as well as methods for separately detecting each of the two markers in stool samples. **D1** does not disclose that the methods provide steps for detecting the combination of the two markers in the same sample. However, this difference does not constitute an inventive step. In view of **D1**, the POSITA would have been aware that both proteins G and U act as markers for the same strain and the POSITA would have come directly and without difficulty to the method of detecting the combination of both G and U within the same stool sample. Therefore, the examiner determines that, in this case, the claim is obvious in view of **D1** and the CGK of the POSITA.

Regarding claim 1 in Example 3:

Statutory subject-matter s2	Y
Novel 28.2(1)	Y
Non-obvious 28.3	**N**

The claim is not allowable as it does not meet all of the requirements of patentability.

Example 4:

The specification describes a method for determining the risk of developing diabetes associated with exposure to persistent organic pollutants (POPs).

- According to the description, the inventors wanted to investigate whether there was a correlation at the molecular level between diabetes and POP exposure.
- The description discloses that the expression levels of five genes were consistently upregulated in patients that had both diabetes and high industrial exposure to POPs as compared to diabetic patients with low POP exposure.
- The description details the steps required for measuring the expression levels of the five upregulated genes in blood samples obtained from patients which included the use of a commercial DNA microarray.
- **D1** discloses a commercial DNA microarray (the same as that exemplified in the instant application) and a summary of the probe sets included on the microarray. Probes for genes T, O, X, I and C were among the 22,000 probe sets on the array.
- **D2-D8** disclose case studies observing that people exposed to POPs have a higher incidence of diabetes than the general population. Thus, the general link between POPs and diabetes is CGK.

Claims:

1. A method for determining the risk of developing persistent organic pollutant (POP)-associated diabetes, comprising:

(a) using a microarray to measure the expression levels of genes T, O, X, I and C in a blood sample obtained from a patient, wherein the microarray comprises oligonucleotide capture probes that are complementary to nucleic acids corresponding to T, O, X, I and C and wherein each probe is attached to a solid support at a discrete position; and

(b) wherein the patient is at risk of developing diabetes if the expression levels of genes T, O, X, I and C are increased relative to the expression levels of the genes in a control sample representative of normal subjects.

2. Use of a microarray to determine the risk of developing POP-associated diabetes by measuring the expression levels of genes T, O, X, I and C in a blood sample obtained from a patient, wherein the microarray comprises oligonucleotide capture probes that are complementary to nucleic acids corresponding to T, O, X, I and C and wherein each probe is attached to a solid support at a discrete position.

3. A microarray comprising oligonucleotide capture probes that are complementary to nucleic acids corresponding to T, O, X, I and C and wherein each probe is attached to a solid support at a discrete position.

Purposive construction for claims 1 and 2:

A purposive construction analysis is set out below for claims 1 and 2 because these claims include both data acquisition and data analysis elements related to medical diagnoses.

As the examiner has determined that claim 3 is not a diagnostic method and defines statutory subject-matter, a purposive construction analysis has not been set out for claim 3. Only the examiner's conclusions as to novelty and inventiveness are provided below for claim 3.

Person of ordinary skill in the art (POSITA)

The POSITA is a team including a medical practitioner, a toxicologist, an endocrinologist and a medical technologist. Further, the POSITA is skilled in gene expression analysis using microarrays.

Common general knowledge (CGK)

The CGK of the POSITA included knowledge of POPs and the health effects associated with POP exposure and bioaccumulation, as well as knowledge of insulin-related metabolic diseases. The link between POP exposure and diabetes was also CGK but the CGK did not include any knowledge of associated genetic markers. The CGK also included the use of commercial microarrays to simultaneously measure the expression levels of a plurality of genes. As admitted in the description, each of genes T, O, X, I and C were represented, amongst thousands of other genes, on a single commercial microarray. It was not CGK, however, to both 1) specifically measure the expression levels of genes T, O, X, I, and C and 2) specifically acquire the data about the expression levels of T, O, X, I and C (while disregarding the levels of all other genes).

The Problem

Considering the specification as a whole and the background of the CGK of the POSITA in the relevant field, the examiner has determined that a problem the inventors set out to address relates to **data acquisition**. Specifically, the identified problem relates to the determination of the expression levels of only genes T, O, X, I and C in a patient's sample.

The Solution

The identified data acquisition problem is solved by the provision of a method that both 1) specifically measures the expression levels of genes T, O, X, I and C, and 2) specifically acquires data about the expression levels of only these genes.

What are the essential elements?

As the solution to the data acquisition problem is provided by step (a) of claim 1, this step is an essential element of claim 1.

In claim 2, elements of the claim that provide means to acquire data about the expression levels of genes T, O, X, I and C are essential because they give the solution to the identified data acquisition problem. However, the use of the microarray to determine the risk of developing POP-associated diabetes is not an essential element of claim 2 because it provides the solution to a data analysis problem.

Statutory subject-matter – section 2

Claims 1 and 2, as construed, are statutory because the essential elements of the claims define subject-matter that falls within a category of invention as defined in section 2 of the Act.

Novelty – subsection 28.2(1)

Claims 1 and 2 are novel. The prior art does not anticipate the construed claim because no single document discloses the essential element of the claims. Although **D1** discloses a microarray that is capable of measuring the expression levels of thousands of genes, including T, O, X, I and C, **D1** does not anticipate claim 1 or 2 because the data set acquired from **D1** is not specific to data about the expression levels of genes T, O, X, I and C alone and **D1** does not teach looking specifically at these particular genes.

Claim 3 lacks novelty in view of **D1**, which discloses and enables a microarray comprising oligonucleotide capture probes that are complementary to nucleic acids corresponding to T, O, X, I and C and wherein each probe is attached to a solid support at a discrete position.

It should be noted that if the term "comprising" in claim 3 was replaced by the term "consisting", claim 3 would be novel if a microarray consisting solely of oligonucleotide capture probes that are complementary to nucleic acids corresponding to T, O, X, I and C was not disclosed in the prior art.

Obviousness – section 28.3

Based on a reading of the specification as a whole from the perspective of the POSITA, in light of their CGK, the inventive concept of claims 1 and 2 is specifically measuring the expression levels of genes T, O, X, I and C in a patient's sample using a microarray comprising oligonucleotide capture probes that are complementary to nucleic acids corresponding to T, O, X, I and C and wherein each probe is attached to a solid support at a discrete position, and specifically acquiring data about the expression levels of these genes. Considering the prior art, it is apparent that the use of commercial microarrays to simultaneously measure the expression levels of a plurality of genes was well known at the claim date. Further, microarrays comprising oligonucleotide capture probes that are complementary to nucleic acids corresponding to T, O, X, I and C were known from **D1.** However, the difference between the prior art and the inventive concept is that the prior art did not disclose that expression level data about **only** T, O, X, I and C was specifically acquired and **D1** did not disregard data about the expression levels of the remaining 22,000 genes on the array. The difference does not constitute a step that would have been obvious to the POSITA. Therefore, claims 1 and 2 are inventive.

Claim 3 is obvious in view of **D1** because it was already determined that the claim was anticipated by **D1** (see MOPOP 15.02.02*d*). For the sake of completeness, the examiner determines that the inventive concept of claim 3 is a microarray comprising oligonucleotide capture probes that are complementary to nucleic acids corresponding to T, O, X, I and C and wherein each probe is attached to a solid support at a discrete position. Prior art document **D1** also discloses and enables a microarray comprising oligonucleotide capture probes that are complementary to nucleic acids corresponding to T, O, X, I and C and wherein each probe is attached to a solid support at a discrete position. It is evident that there is no difference between the inventive concept of claim 3 and **D1** and, therefore, the POSITA would not have required any degree of invention to arrive at the inventive concept.

Regarding claim 1 in Example 4:

Statutory subject-matter s2	Y
Novel 28.2(1)	Y
Non-obvious 28.3	Y

Regarding claim 2 in Example 4:

Statutory subject-matter s2	Y
Novel 28.2(1)	Y
Non-obvious 28.3	Y

Regarding claim 3 in Example 4:

Statutory subject-matter s2	Y
Novel 28.2(1)	**N**
Non-obvious 28.3	**N**

The application is not allowable as claims 2 and 3 do not meet all of the requirements of patentability.

17.04
Sufficiency of the description – January 2009

Closely related to the question of utility is that of sufficiency. Subsection 27(3) of the *Patent Act* requires (*inter alia*) that the description "correctly and fully describe the invention and its operation or use as contemplated by the inventor". Thorson P. summarized the requirements for sufficient specification in *Minerals Separation North American Corp v Noranda Mines, Ltd*, and later described this "onus of disclosure" as "a heavy and exacting one"..[1]

The description must be correct; this means that it must be both clear and accurate. It must be free from avoidable obscurity or ambiguity and must be as simple and distinct as the difficulty of description permits. It must not contain erroneous or misleading statements calculated to deceive or mislead the persons to whom the specification is addressed and render it difficult for them without trial and experiment to comprehend in what manner the invention is to be performed. It must not, for example, direct the use of alternative methods of putting it into effect if only one is practicable, even if persons skilled in the art would be likely to choose the practicable method. The description of the invention must also be full; this means that its ambit must be defined, for nothing that has not been described may be validly claimed..[2]

As was noted in section12.04.03c, the description must contain sufficient information to support a sound prediction of the utility of the invention. Further, it must set out the invention such that a person skilled in the art can practice it having reference only to the description itself and to common general knowledge.

In *Consolboard*, Dickson J. noted that "the inventor must, in return for the grant of a patent, give to the public an adequate description of the invention with sufficiently complete and accurate details as will enable a workman, skilled in the art to which the invention relates, to construct or use that invention when the period of the monopoly has expired"..[3] The description must be able to answer the questions "What is your invention?: How does it work?".[4] such that "when the period of the monopoly has expired the public will be able, having only the specification, to make the same successful use of the invention as the inventor could at the time of his application"..[5]

A description sufficient to allow the public (in the form of a person skilled in the art) to practice the invention is said to be enabling. Since the person skilled in the art is the addressee of the description, it is not necessary for common knowledge to be comprehensively disclosed. A known assay technique does not need, for example, to be taught in full. Merely referring to this technique is sufficient for the person skilled in the art to know how to practise it.

When an examiner has reason to believe that a description is deficient for not having correctly and fully described the claimed invention, an objection is raised under subsection 27(3). This might be the case, for example, when a broad claim is supported only by its own verbatim language.

It is important to bear in mind that the specification must be sufficient to allow the full scope of the claimed invention to be practised without the need for the person skilled in the art to exercise their inventive ingenuity. If the person skilled in the art is called on to solve problems in such a manner that an inventive step would be present, the description is insufficient (and the attendant claims are unsupported).

17.05
Nucleic acids and proteins – March 2016

The following subsections relate to issues regarding nucleic acids, polynucleotides, peptides, polypeptides and proteins and the disclosure of their sequences in a sequence listing.

17.05.01
Defining by structure – March 2016

Generally a product may be defined by its structure, in terms of the process by which it is made, or in terms of its physical or chemical properties. Often the most explicit and definite manner in which to define a chemical compound is by its structure.

For a biomolecule such as a nucleic acid molecule or protein, the structure is typically represented by the nucleotide or amino acid sequence, e.g., "a polypeptide consisting of the amino acid sequence MARNDCQEGHILKFPSTWYV".

For greater clarity, the claim should be explicitly directed to a biomolecule defined by reference to a sequence listing identifier that points to the corresponding sequence in the sequence listing [see 17.05.07], e.g., "a nucleic acid consisting of the nucleotide sequence represented by SEQ ID NO:1" or "a protein comprising the amino acid sequence set forth in SEQ ID NO:2". A claim simply directed to a sequence listing identifier, however, may be interpreted as a claim to mere information (i.e., to the string of letters depicted in the sequence listing), which is not compliant with section 2 of the *Patent Act*, rather than a claim to the biomolecule itself. A claim directed to "SEQ ID NO:8", for example, would be unacceptable but a claim to "DNA encoding the protein comprising amino acids 1-260 of SEQ ID NO: 8" would be unambiguous (assuming the reference sequence is clearly defined – see below).

Note that even where a claim to a biomolecule is defined by reference to a sequence within the sequence listing it is not an assurance that the claimed biomolecule will be adequately defined by structure. For example, where a biomolecule is defined in a claim by reference to a sequence that contains a number of variable symbols such as "Xaa" or "n", the claimed subject-matter may not be defined in distinct and explicit terms and may fail to comply with subsection 27(4) of the *Patent Act*.

In the case of a nucleic acid molecule defined by the protein it encodes, the provision of a partial amino acid sequence of the protein is not taken as an adequate description of a nucleic acid molecule which is capable of encoding the entire protein..[1]

17.05.02
Defining by functional limitation – March 2016

Functional language is generally used to provide breadth to a claim. In certain cases, language that defines specific functional or biological activity may be used to further distinguish a claimed biomolecule from biomolecules of the prior art. Although the use of functional language does not make a claim defective *per se*, if it is used then the entire scope of the claim must be clear and fully supported by the description [see Chapter 9 of this manual for more information].

In general, the use of functional language in a claim is acceptable if the person skilled in the art would not need to resort to inventive ingenuity to practise the full scope of the claim. For example, consider a claim to "a plant transformation vector comprising a gene of interest; a transposon; and a marker gene positioned within the transposon, wherein the marker gene induces abnormal cellular differentiation in plant tissue".

Assuming that representative marker genes are adequately supported in the description and are well known in the prior art by persons skilled in the art, it is acceptable in this case to define the marker gene in functional terms.

On the other hand, where the use of functional language requires the person skilled in the art to exert an inventive effort to practise the full scope of the claim or, likewise, the use of the language causes the scope of the claim to be overly-broad, the claim is likely defective in view of section 84 of the *Patent Rules.* Where the examiner determines that the description is insufficient to support the breadth of the claim, depending on the facts, a defect could be identified under subsection 27(3) of the *Patent Act*. Where knowledge of the structure of the protein or nucleic acid is needed to realize the full scope of the claim, the claim may also lack compliance with subsection 27(4) of the *Patent Act* if the nucleic acid or protein is not further defined by the structure that provides the functional activity.

In the case where, for example, the structure of a protein (or a nucleic acid encoding a protein) is defined in terms of a percent identity to a reference sequence, the claim should additionally specify that the protein has the same biological activity as that described in the application in order to comply with subsection 27(4) of the *Patent Act*– e.g., "a nucleic acid comprising a sequence that is at least 90% identical to SEQ ID NO:1 *which encodes a protein having alpha-amylase activity*".

Example:

An application describes a novel polypeptide depicted in the sequence listing as SEQ ID NO:2 that has xylanase activity and is shown to be particularly effective in processes for making biofuels. The description does not describe any variants of the polypeptide having xylanase activity. A search of the prior art revealed that xylanases are generally known. A search for the amino acid sequence of SEQ ID NO:2 identified prior art documents D1 and D2. D1 discloses a polypeptide having 82% sequence identity to SEQ ID NO:2 but lacking xylanase activity while D2 discloses a xylanase having 92% sequence identity with SEQ ID NO:2.

Claims:

1. A recombinant polypeptide having xylanase activity.

2. A recombinant polypeptide comprising an amino acid sequence that is at least 80% identical to SEQ ID NO:2.

Analysis: claim 1 is defective. The claimed polypeptide is defined broadly by a functional description of its activity rather than by its structural features. The description discloses with particularity only one polypeptide; this polypeptide is described as having the structural features depicted in SEQ ID NO:2 and the desired xylanase activity. Given that the claim defines more than the description supports, the claim is defective in view of section 84 of the *Patent Rules*. Where the examiner determines that the description is insufficient to support the breadth of the claim, depending on the facts a defect could be identified under subsection 27(3) of the *Patent Act*. The subject-matter of the claim also lacks novelty in view of D2 (in effect, the claim would be anticipated by any earlier public disclosure of a polypeptide having the desired activity). D1, on the other hand, would not be anticipatory to claim 1 since D1 does not disclose a polypeptide having the specified activity. Furthermore, if, having regard to the claim and description, it is not clear to the skilled person what is being claimed then a defect under subsection 27(4) of the *Patent Act* may also be identified.

Claim 2 is defective on multiple grounds. The polypeptide is defined in terms of its structure and, more particularly, to the minimum threshold of percent identity of the structure to the amino acid sequence of SEQ ID NO:2. In this case the claim defines more than the description supports and does not comply with section 84 of the Rules. Given that claim 2 does not define the functional activity of the polypeptide, the claim potentially encompasses polypeptides that lack xylanase activity and/or have unknown function. Identification of a defect under subsection 27(4) of the Patent Act may be warranted where it is unclear whether what is being claimed has the same functional activity as the polypeptide of the application. In addition, the claim is defective for lacking novelty in view of either D1 or D2, which each disclose and enable a polypeptide comprising an amino acid sequence that is “at least 80% identical to SEQ ID NO:2”. Had claim 2 included a functional limitation to xylanase activity then D1 would not have been anticipatory.

17.05.03
Nucleic acid and amino acid terminology – March 2016

Nucleotide or amino acid sequences referred to as being “substantially identical” to a target sequence are not adequately defined since there is no accepted convention in the art as to what is encompassed by the term “substantially” and since the scope of a claim may vary depending on what one considers to be a “substantially” identical sequence.

A nucleotide or amino acid sequence may be defined by a threshold percentage limit as compared to a target sequence – e.g., a nucleic acid molecule comprising a nucleotide sequence that is at least 95% identical to the sequence of SEQ ID NO: 7. If the term “homology” is used to describe the relationship between the sequence and the target then the claim is considered indefinite since the term implies an evolutionary relationship which either exists or does not exist..[2] Applicants are generally permitted to replace the term "homology" with the term "identity" for greater clarity. A defect under subsection 27(4) of the *Patent Act* may also be identified where a claim includes the term "similarity" and there is no clear definition of what the applicant considers to be similar residues.

17.05.04
Hybridizing nucleic acids – March 2016

Nucleic acids are often defined as sequences that hybridize to a particular target sequence under various reaction, or stringency, conditions. Given that there is no clear consensus as to what conditions are best used in a given hybridization reaction and that different reaction conditions will capture different nucleic acids, a claim may be held to be indefinite for failing to define the particular parameters to be used during the hybridization reaction and ensuing washings.

Where the target itself is solely defined as being any member of a large family of nucleic acids, e.g., a family of degenerate nucleic acids or variants encoding the same amino acid sequence (including nucleic acids defined as having less than 100% identity), the scope of a claim to a nucleic acid molecule that hybridizes to such a target becomes unclear. In such cases, the target is not limited to a single clearly-defined nucleic acid but instead encompasses a vast number of possible combinations of hybridizing and target nucleic acids.

Where a claim suggests that a nucleic acid molecule, which hybridizes to a target sequence encoding a functional polypeptide, is itself also capable of encoding a functional polypeptide, the claim may be held to be defective under subsection 27(4) of the *Patent Act* since hybridizing nucleic acids may either not encode a polypeptide, or encode a polypeptide having a different function than that encoded by the target. For greater clarity, such claims should indicate that the nucleic acid molecule hybridizes to the *complement* of the target sequence.

17.05.05
Sequence alignment methods – March 2016

Whenever a sequence is identified as having a certain percent identity to a reference sequence, it is necessary to define in the claim whether the percent identity is relative to the full length of the reference sequence or is a partial alignment (such as a BLAST alignment[3]).

For the sake of clarity, alignment of the sequence over the full length of the reference sequence is greatly preferred when making the comparison.

17.05.06
Considerations respecting obviousness – March 2016

In accordance with section 28.3 of the *Patent Act*, an invention as claimed cannot be obvious or, equivalently, must be the result of ingenuity.[4] [see Chapter 15 of this manual for further guidance].

If given the amino acid sequence of a polypeptide, the entire class of nucleic acids encoding it can be generated through simple deduction; i.e., by using the genetic code to back-translate from the amino acid sequence. Therefore, where protein X is known in the prior art, a broad claim to "a nucleic acid encoding the amino acid sequence of protein X", for example, is considered obvious.

The opposite is also considered obvious. An amino acid sequence encoded by a known nucleic acid can be directly derived through the translation of the known coding nucleotide sequence provided the correct reading frame has been identified or is obvious.

Given that the class of nucleic acids encoding any particular polypeptide is astronomically large, the identification of a species of the class which has unexpected or advantageous properties can be inventive. Such claims should be analyzed in the context of a selection [see Chapter 15 of this manual].

Example:

An application discloses that a nucleic acid molecule (SEQ ID NO:7) is particularly advantageous for expression in plant tissue and encodes a peptide having the amino acid sequence set forth in SEQ ID NO:8. Prior art document D1 discloses the amino acid sequence of peptide G, which is identical to SEQ ID NO:8, but was derived through Edman degradation. There are no indications in D1 that recombinant techniques were used nor is there an explicit disclosure of a nucleic acid molecule which encodes peptide G. Review article D2 discusses methods and codon usage tables that may be used in order to achieve enhanced expression of heterologous genes in plant tissues.

Claims:

1. A nucleic acid encoding the peptide identified by SEQ ID NO:8.

2. A nucleic acid which has been optimized for expression in plant tissue and which encodes the peptide identified by SEQ ID NO:8.

3. A nucleic acid comprising the sequence identified by SEQ ID NO: 7 which has been optimized for expression in plant tissue and which encodes the peptide identified by SEQ ID NO: 8.

Analysis: Although it is recognized that obviousness inquiries should follow a four-step approach,[5] the analysis has been simplified for the purposes herein.

Claim 1 is obvious in view of D1. Firstly, the claim does not refer to any nucleic acid in particular and merely reflects the general idea of having a nucleic acid molecule which is capable of encoding the peptide; an idea that a person of skill in the art would readily appreciate in view of D1. Second, D1 provides the amino acid sequence of the peptide making it a simple matter of deduction for the person of skill in the art to generate a nucleotide sequence capable of encoding the peptide. Therefore, claim 1 fails to satisfy section 28.3 of the *Patent Act* in view of the teachings of D1.

Claim 2 is obvious in view of D1 in combination with D2. The claim does not refer to any nucleic acid in particular and merely reflects, albeit in a somewhat more restricted sense, the general idea of having a nucleic acid molecule which has been optimized for expression in plant tissue; an idea that a person of skill in the art would readily be able to put into practical effect by deducing an appropriate encoding sequence from D1 in view of the more specific guidance offered by D2.

Claim 3 is not obvious since neither D1 nor D2 discloses nor suggests the particular sequence referred to in the claim (SEQ ID NO:7). Given that it is disclosed that the sequence has a substantial advantage, the claim represents the selection of nucleic acids having a particular sequence from amongst the genus of all possible nucleic acids encoding the peptide and from amongst the subgenus of all possible nucleic acids employing plant optimized codons.

17.05.07
Sequence listings – April 2018

An application that discloses a nucleotide or amino acid sequence, other than one that belongs to the prior art, must contain a sequence listing. In some cases, the provision of a sequence listing may be needed to satisfy administrative requirements (e.g., sections 94 and 111 of the *Patent Rules*), and to "correctly and fully describe the invention and its operation or use as contemplated by the inventor" (i.e., subsection 27(3) of the *Patent Act*).

The following subsections apply to applications filed on or after June 2, 2007. For applications filed prior to that date, the applicant may substitute the requirements of sections 111 to 131 of the *Patent Rules* as they read immediately prior to the coming into force of the current rules for the requirements of current section 111 of the *Patent Rules*. Similarly, the requirements of section 62 as it read immediately prior to the coming into force of the current rules may be substituted for the requirements of current section 94 of the *Patent Rules*.

17.05.07*a*
Requirements for a sequence listing

In accordance with subsection 111(1) of the *Patent Rules*, if an application discloses "a nucleotide or amino acid sequence other than a sequence identified as forming a part of the prior art, the description shall contain, in respect of that sequence, a sequence listing in electronic form, and both the sequence listing and the electronic form shall comply with the PCT sequence listing standard".

When this is the case, the provision of the sequence listing is a requirement for completion of the application (whether or not the application is a PCT national phase application). Section 94 of the *Patent Rules* requires that the sequence listing be provided to the Office within the later of twelve-months from filing or three months from the date of receipt of a notice requisitioning its provision. An applicant may not request the sequence listing from another application be brought forward and recorded against the application since the Office does not consider that such a request satisfies the requirements of section 94 and subsection 111(1) of the *Patent Rules*.

The applicant must provide any required sequence listing within "the applicable time" to avoid the payment of the fee set out in item 2 of Schedule II. For an application other than a PCT national phase application, the applicable time is 15 months from the earliest priority date or, where no priority is claimed, 15 months from the filing date. For a PCT national phase application, the applicable time is 3 months from payment of the requisite fees for national entry and provision of a copy of the application and/or a translation of the application if applicable (i.e., the requirements of subsections 58(1) and 58(2) of the *Patent Rules*).

When a sequence listing submitted in accordance with subsection 111(1) of the *Patent Rules* is of record in the Office, it is not permissible for a paper copy of the sequence listing to be of record. Applicants will be requisitioned to withdraw any paper copy of a sequence listing for which a PCT sequence listing standard-compliant electronic sequence listing has been made of record.

In accordance with subsection 111(2), if a sequence listing is added to an application originally filed without a sequence listing, "the applicant shall file a statement to the effect that the listing does not go beyond the disclosure in the application as filed".

17.05.07*b*
The PCT sequence listing standard

The term "PCT sequence listing standard" refers to the Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in International Patent Applications Under the PCT. This standard is provided in annex C of the Administrative Instructions under the PCT and is available via the World Intellectual Property Organization (WIPO) website.

As per subsection 111(3) of the *Patent Rules,* if an application as filed contains a sequence listing that does not comply with the PCT sequence listing standard and the applicant replaces the non-compliant sequence listing with one that does comply with that standard, the applicant shall file a statement to the effect that the replacement listing does not go beyond the disclosure in the application as filed.

17.05.07*c*
Presentation of sequences

Each nucleotide or amino acid sequence disclosed in an application, other than a sequence identified as forming a part of the prior art, is assigned a separate sequence identifier in the sequence listing. The sequence identifier is a unique integer that appears beside numeric identifiers <210> and <400> in the sequence listing for each sequence. The sequence identifiers begin with 1 and increase in sequential order.

In cases where no nucleotide or amino acid sequence is present for a given sequence identifier, the code 000 should appear beneath numeric identifier <400>, beginning on the next line following the sequence identifier.

Except in situations where the entire sequence listing is removed from the application, the original sequence identifier assigned to a given sequence should be maintained even after amendment of the application. Thus, in cases where a nucleotide or amino acid sequence is removed from the sequence listing by amendment, the nucleotide or amino acid sequence originally presented beneath numeric identifier <400> should be replaced with code 000. In such cases, only data for numeric identifiers <210> and <400> are required. It is noted that the removal of the subject-matter from the description should not cause the application to become non-compliant with subsection 27(3) (see 17.05.07) or subsection 38.2(2) of the *Patent Act* (see Chapter 19 of this manual for further guidance on amendments to patent applications). Additionally it should be noted that when removing sequences from the sequence listing, any references in the specification to the associated sequence identifiers should also be deleted.

Numeric identifier <160>, which precedes the presentation of the actual nucleotide and/or amino acid sequences of the application, represents the total number of sequence identifiers in the sequence listing including those having code 000 at <400>.

Please consult the PCT sequence listing standard available via the WIPO website for more information about numeric identifiers and the presentation of sequences.

Example:

The originally-filed sequence listing featured three DNA sequences. The sequence listing below has been correctly amended to remove the DNA sequence originally identified as SEQ ID NO:2 in the application.

```
SEQUENCE LISTING

<110>  Applicant ABC
<120>  Title of the invention
<160>  3
```

```
<210>  1
<211>  24
<212>  DNA
<213>  Castor canadensis
<400>  1
gcattaccat atgccctagg tttt
```

```
<210>  2
<400>  2
 000
```

```
<210>  3
<211>  19
<212>  DNA
<213>  Castor canadensis
<400>  3
attcccgggg attcccggg
```

17.05.07*d*
Identification of a sequence listing

In accordance with subsection 86(3) of the *Patent Rules*, the claims may refer to sequences represented in the sequence listing by the sequence identifier and preceded by “SEQ ID NO:”. The sequence identifier has the same meaning as in the PCT sequence listing standard according to subsection 86(3.1) of the *Patent Rules*.

17.05.07*e*
Variable symbols in a sequence listing

The use of the symbols “n” (or “N”) and “Xaa” to define “unknown or modified” bases and amino acids, respectively, is discussed in paragraphs 10 and 18 of the PCT sequence listing standard. When these symbols are used in a sequence listing, they can represent only a single residue (nucleotide or amino acid, respectively) at a specific position in the sequence.

The Office considers that the residues represented by the symbols “n” (or “N”) and “Xaa” may be defined in the “Features” section as being either present or absent, and that these symbols may also be used to define that a standard nucleotide or amino acid residue is either present or absent. Similarly, these symbols can be used, through the definitions given in the “Features” section, to represent alternate residues at a given position.

Note that since such symbols represent only a single residue, a sequence of variable length must be presented by using a sufficient number of discrete symbols to represent the maximum length of the sequence. Symbols used in such a presentation may then be qualified in the "Features" section to be either present or absent.

The foregoing discussion relates only to the manner in which the foregoing symbols may be used as a matter of nomenclature. During examination, an examiner must consider whether or not the use of such symbols contravenes the *Patent Act* and/or *Rules*, for example on the basis of clarity or support [see 17.05.01].

17.05.07*f*
Correction of a sequence listing

If a sequence listing is found to contain errors, any correction of the listing must comply with the requirements of subsection 38.2(2) of the *Patent Act*. That is, no new matter may be added to the specification or drawings as originally filed and any correction made to a sequence listing must be reasonably inferable from the specification or drawings as filed. Where the corrected sequence could only be determined by, for example, re-sequencing a sample, the correction is not reasonably to be inferred.

17.06
Deposits of biological materials – March 2016

Deposits of biological material are addressed in the *Patent Act* at subsections 38.1(1) and (2). Note that for the purposes of section 38.1, the term "biological material" may include bacteria, bacteriophages, cells in culture, hybridomas, filamentous fungi, yeasts, plant seeds, viruses, purified nucleic acid molecules, plasmids, and replication-defective cells.

Subsection 38.1(1) of the *Patent Act* provides that:

Where a specification refers to a deposit of biological material and the deposit is in accordance with the regulations, the deposit shall be considered part of the specification and, to the extent that subsection 27(3) cannot otherwise reasonably be complied with, the deposit shall be taken into consideration in determining whether the specification complies with that subsection.

Subsection 38.1(2) of the *Patent Act* provides that:

For greater certainty, a reference to a deposit of biological material in a specification does not create a presumption that the deposit is required for the purpose of complying with subsection 27(3).

Where a specification refers to a deposit, the deposit shall be considered part of the specification if it is in accordance with the regulations. Sections 103 to 110 of the *Patent Rules* regulate deposits of biological material. In particular, subsection 104(1) requires the deposit to be made by the applicant with an international depositary authority on or before the filing date of the application. Before the application is open to public inspection, the applicant must inform the Commissioner of the name of this authority and the accession number given to the deposit as per subsection 104(2). The description must include this information and the date of the original deposit with the authority. Further practical aspects of the *Patent Rules* are covered in Appendix 1 of this chapter.

17.06.01
Considerations respecting sufficiency of disclosure

Bearing in mind that a specification must both adequately describe and enable an invention in order to satisfy subsection 27(3) of the *Patent Act* so that "when the period of the monopoly has expired the public will be able, having only the specification, to make the same successful use of the invention as the inventor could at the time of his application",[1] sufficiency must be considered where the specification refers to a biological deposit. The considerations respecting sufficiency of disclosure as a requirement for patentability are more fully addressed in Chapter 9 of this manual.

A deposit of biological material may be made whether or not it is necessary to enable the invention as required per subsection 27(3) of the *Patent Act*. However, where the invention cannot be enabled in the absence of access to a biological material, the deposit is a necessary element to make the description sufficient unless the required material is publicly known and reliably available to the person skilled in the art. A biological material is considered to be reliably available if it can be obtained commercially or can be reproducibly prepared or isolated from available materials using established procedures and without undue experimentation. In the case of plant seeds, the Office considers a seed to be reliably available where it enables one to obtain, in a reproducible manner, a homogeneous population of plants that are identical to the plant of the invention.

The fact that a biological deposit has been made does not of itself mean that an invention has been adequately described.[2] A claim to a desired product does not merit protection simply because reference is made to where the product can be found. Thus, if it is possible to define the product in clear and explicit terms, a deposit is not considered a substitute for a full and correct description of the product itself and, in view of subsection 38.1(1) of the *Patent Act*, would not of itself meet the requirements of subsection 27(3) of the *Patent Act*.

Whenever possible, it is preferable that both methods of disclosure should be used[3] (i.e., disclosures relating to both the deposit of biological material and a clear and explicit description of the product or process of making the product).

Example:

The specification as filed describes both a new mutant strain of bacteria, which is useful for treating gastrointestinal disorders, and a nucleic acid molecule isolated from the strain. The description includes the dates of the original deposits with the international depositary authority and the corresponding accession numbers of both the strain and plasmid comprising the nucleic acid molecule.

Claims:

1. A *Bifidobacterium* sp. strain having probiotic activity for treating gastrointestinal disorders, which is deposited under ATCC-8888.

2. An isolated nucleic acid molecule selected from the group consisting of:

    a) the DNA insert of the plasmid deposited under ATCC-9999; and

    b) the DNA included in the strain of claim 1.

Analysis: claim 1 features a bacterium strain, which is partly defined by reference to its biological deposit number. In this case, recognizing that it is not always possible to describe the matter in terms of its structure and/or physical characteristics, a description of the biological deposit in the description provides a sufficient disclosure of the claimed strain and, therefore, satisfies subsection 27(3) of the *Patent Act*.

Claim 2 is directed to an uncharacterized nucleic acid molecule defined by reference to biological deposits containing the molecule. Given that it is possible to define the nucleic acid molecule in clear and explicit terms (e.g., by its DNA sequence) and despite the fact that the skilled person in the art may be able to isolate the molecule from the deposit and characterize it (e.g., determine its sequence), the mere inclusion of the deposit information in the specification is not a substitute for a full and correct description of the molecule itself. In the absence of a disclosure of the DNA sequence of the molecule in the specification, subsection 27(3) of the *Patent Act* is not satisfied. The claim may also be considered non-compliant with subsection 27(4) of the Act since the claimed subject-matter is not defined in distinct and explicit terms.

17.06.02
Considerations respecting anticipation

Where an invention cannot be enabled without requiring access to a biological material associated with the invention, a description may lack sufficiency unless a deposit of this material was made [see 17.06.01]. This requirement extends to an allegedly anticipatory disclosure relevant under section 28.2 of the *Patent Act* [see Chapter 15 for further guidance]. Consequently, if a prior art disclosure requires access to a biological material in order for the matter described therein to be practised, the biological material must necessarily have been reliably available to the person skilled in the art before the claim date in order for the disclosure to be anticipatory.

Example 1:

An application claims a mutant strain of *Citrobacter* sp. that is able to effectively remove mercury from wastewater. The description provides details of the biological deposit of the strain with an international depositary. A search of the prior art reveals document D1, which discloses an isolated bacterial strain of *Citrobacter* sp. that has an ability to degrade mercury but does not describe a biological deposit or how to otherwise obtain the strain.

Claims:

1. A biologically pure culture of a strain of *Citrobacter* sp. having mercury-degrading activity.

2. The culture of claim 1 wherein the strain is deposited under NCIMB Accession No. 24601.

Analysis: prior art document D1 *discloses* a strain that falls within the scope of claim 1; however, D1 is not *enabling* since the strain is not reliably available to the person skilled in the art. The strain is further defined in claim 2 by reference to a particular biological deposit, which is neither disclosed nor enabled in D1. Thus, the subject-matter of the claims is not anticipated by D1. It is noted that the examiner may additionally determine that the claims are defective in view of section 84 of the Rules and/or subsection 27(4) of the Act.

Example 2:

An application discloses plasmid Y and provides details of its biological deposit with an international depositary. Prior art document D2 describes “plasmid X”, which was constructed from various known genetic elements using known methods. Plasmid X was not deposited but the genetic elements used to construct it were all freely available to the public.

Claim:

1. Plasmid Y [which has the same elements and arrangement as prior art plasmid X] deposited as IDAC 314159-26.

Analysis: the claim is anticipated since claimed plasmid Y is indistinguishable from known plasmid X. Further, a person of skill in the art would be enabled to construct plasmid Y using known, freely available, genetic elements and methods. The fact that the plasmids do not share the same name does not negate the finding of anticipation.

17.07
Antibodies - November 2017

Antibodies, as a class of chemical compounds, have been structurally and functionally well-characterized. The structure of an antibody relates directly to its biological function, including its binding specificity and affinity to its target antigen. Structurally, each antibody is composed of light and heavy polypeptide chains where each chain has variable and constant regions. The variable regions comprise subregions involved in antigen binding, which are known as the complementarity determining regions (CDRs).

It is well established in the art that the formation of an intact antigen binding site generally requires the association of the complete heavy and light chain variable regions of a given antibody, each of which consists of three CDRs which provide the majority of the contact residues for the binding of the antibody to its target epitope. Given that the sequences of the CDRs are responsible for the specific binding of the antibody to its antigen, small changes to those sequences may significantly and unpredictably alter binding specificity and affinity. Therefore, it is generally expected that all of the heavy and light chain CDRs in their proper order and in the context of framework sequences which maintain their required conformation, are required in order to produce an antibody and that proper association of heavy and light chain variable regions is required in order to form functional antigen binding sites.

It is known that, in general, immunization of a mammal with an antigen results in the production of an antiserum containing a heterogeneous mixture of antibodies in which individual antibodies bind to different regions displayed on the surface of the immunizing antigen (i.e., an epitope or antigenic determinant). Thus, antiserum comprises an entire family of antibodies capable of binding to different epitopes on an antigen.

An antibody is often defined in functional terms by its specific binding to a particular target antigen. A claim directed to “an antibody which specifically binds to antigen X” typically represents a generic group of structurally different antibodies having common binding specificity to the antigenic target. This contrasts with a claim to a particular antibody which has been defined in terms of a property of the antibody itself rather than merely by what it binds (for example, the particular antibody is defined in terms of its encoding DNA/protein sequence, or by reference to a biological deposit that was made in accordance with the *Patent Rules*). Thus a claim to “an antibody which specifically binds to antigen X” is considered to be a claim to a generic group of structurally different antibodies having said binding specificity. Conversely, a claim to “an antibody which specifically binds to antigen X wherein said antibody has a heavy chain encoded by a nucleic acid of SEQ ID NO: 1 and a light chain encoded by a nucleic acid of SEQ ID NO:2” or a claim to “an antibody which specifically binds to antigen X and is produced by a hybridoma having accession number ABC-123”, encompasses only the particular antibody, i.e. is not a claim to a generic antibody.

A claim to an antibody, as with a claim to any other subject-matter, must be supported by a specification that satisfies subsection 27(3) of the *Patent Act*. In the case of antibodies, this means that at the relevant date, which is deemed to be the filing date[1], the specification must:

- **correctly and fully describe** the antibody invention and its operation or use as contemplated by the inventor; and
- set out clearly the various steps in a process, or the method of making or using the antibody, in such full, clear, concise and exact terms as to **enable** any person skilled in the relevant art to make or use it.

Generally, a claim to an antibody specific for antigen X will be considered supported by a specification provided:

(i) antigen X itself has been fully characterized; and

(ii) either antiserum has been prepared, or where antiserum has not been prepared, there is neither anything peculiar about the antigen nor any indications that would lead a person of skill in the art to question the likelihood of success if that person desired to produce an antibody to the antigen.

The claims must also **distinctly** and **explicitly** define subject-matter that is **novel**, **non-obvious**, **useful** and **statutory**.

If antigen X is known or obvious in view of the prior art then an antibody reactive with that antigen would generally be considered obvious.

Where the prior art discloses and enables antibodies reactive with a close structural relative of antigen X, then a claim to an antibody reactive with antigen X (e.g. an antibody "capable of binding" or "that specifically binds" to antigen X) will be anticipated if the claim, upon a purposive construction, is construed to encompass cross-reacting antibodies of the prior art.

An antibody invention must also be useful. An inventor need not expressly set out the utility of the antibody in the specification; however, if the invention's utility is questioned, then it must be demonstrated or soundly predicted as of the application's filing date in order to comply with section 2 of the *Patent Act* (for further guidance see 17.07.05).

Example:

The description discloses a novel protein that has utility as a diagnostic target for detecting a disease caused by a pathogenic bacterium. Also disclosed are the amino acid sequence of the protein (SEQ ID NO:2), methods of purifying the protein using recombinant techniques, and reference to routine methods of preparing antibodies to a protein by immunizing a suitable mammalian host. The description is silent as regards the production of any antibodies and lacks any working examples of an antibody specific to the protein.

Claim:

> 1. An antibody that specifically binds to a protein consisting of the amino acid sequence set forth in SEQ ID NO:2.

Scenario 1

A search of the prior art for the sequence depicted in SEQ ID NO:2 reveals that the closest structural relative to the protein is 20% identical with no common domains of any significance.

Analysis: the claim is fully supported by a specification that satisfies subsection 27(3) of the *Patent Act* because the specification is enabling with respect to preparing antibodies and the scope of the claim in respect of the antigenic target is limited to the fully characterized protein of SEQ ID NO:2 which serves as a correct and full description of the corresponding antibody that specifically binds to it. Recognizing that the antigenic protein (SEQ ID NO:2) is not disclosed in the prior art, it follows that the claimed antibody, which specifically binds this protein, is novel and non-obvious. The protein (SEQ ID NO:2) itself has utility as a diagnostic target and antibodies that bind the protein serve a specific useful purpose. Further, the subject-matter of the claim is defined in distinct and explicit terms. Therefore, the claim complies with the *Patent Act* and *Rules*.

Scenario 2

A search of the prior art for the sequence depicted in SEQ ID NO:2 reveals that the protein is a low-molecular-weight member of a class of known proteins. Prior art document D1 teaches that antibodies to this class of proteins have never been prepared despite several attempts.

Analysis: the description is silent as regards the successful production of antibodies against the protein of SEQ ID NO:2. Considering that D1 discloses that, despite several attempts, antibodies have never been raised against proteins of a similar type, the person skilled in the art would not regard the instant specification as sufficient to enable the production of the claimed antibody. Thus, paragraph 27(3)(*b*) of the *Patent Act* is not satisfied. It is noted that the antibody of claim 1 is otherwise correctly and fully described by way of the disclosure of the fully characterized antigen to which it specifically binds.

17.07.01
Polyclonal antibodies – January 2017

Polyclonal antibodies can be thought of as a generic group that is representative of the entire family of antibodies in antiserum capable of binding a target antigen. Polyclonal antibodies share specificity to the target antigen yet each individual antibody can differ in regard to which epitope on the antigen it specifically binds.

Methods for preparing polyclonal sera are well known in the art and a specification generally does not need to describe in detail any of these methods to be enabling with respect to paragraph 27(3)(*b*) of the *Patent Act*.

With respect to a correct and full description of the invention pursuant to paragraph 27(3)(*a*) of the *Patent Act*, an antibody, like any other chemical compound, can be described in terms of its chemical structure; however, polyclonal antibodies are not described this way. Rather, it has become accepted practice to describe polyclonal antibodies in terms of the fully characterized antigen to which they specifically bind, e.g., “an antibody that specifically binds to antigen X”. Recognizing that an antigen is implicitly understood to carry many epitopes, a fully characterized antigen is representative of the collective of epitopes carried on the target antigen and therefore provides a correct and full description of the corresponding polyclonal binding partners.

For the purposes of paragraph 27(3)(*a*) of the *Patent Act*, a disclosure of an antigen’s chemical structure may be enough to fully characterize the antigen. Where the antigen is a protein, for instance, a description of its complete amino acid sequence is likely adequate. In some cases, a description of the antigen in other terms, such as formula, chemical name, physical properties or by biological deposit, may be adequate provided that the person skilled in the art understands the scope of the antibody claim through the unique physical or chemical properties of the antigen.

If antigen X is known or obvious in view of the prior art then polyclonal antibodies reactive with that antigen would generally be considered obvious.

A polyclonal antibody invention must also be useful (for further guidance see 17.07.05).

17.07.02
Monoclonal antibodies – January 2017

A monoclonal antibody binds to a specific epitope or antigenic determinant carried on an antigen. A monoclonal antibody can be viewed as one member of the family of polyclonal antibodies contained in antiserum produced by an immunizing antigen. For specific guidance respecting humanized and chimeric monoclonal antibodies, see 17.07.03.

17.07.02*a*
Sufficiency of the disclosure

As with claims to polyclonal antibodies, a claim to a monoclonal antibody must be supported by a specification that is both enabling and includes a correct and full description of the antibody invention. Sufficiency of disclosure is based on a fact-specific determination..[2]

The common general knowledge of the person skilled in the art is an important factor for assessing whether the specification of an application is sufficient to enable the skilled person to practise the invention. Generally, the specification need not set out a detailed procedure for producing a monoclonal antibody since the core steps for preparing a monoclonal antibody are now well known to a skilled person in the art. A description of a detailed step-by-step protocol would be necessary, however, if the invention resides, at least in part, in an applicant having inventively adapted known procedures to overcome some difficulty in making a monoclonal antibody to a particular antigen.

Although each application will be considered on its own merits, the following non-exhaustive list of factors should be considered by examiners when determining whether claims to monoclonal antibodies are **enabled** by a specification:

- whether the applicant actually prepared a monoclonal antibody;
- where a monoclonal antibody had not been prepared,
    - whether the target antigen to which the monoclonal antibody specifically binds was fully characterized,
    - the availability and/or ease of production of the antigen,
    - whether there is an absence of any indications that the applicant was unable to produce a monoclonal antibody or that one of skill in the art would be unable to reproducibly make a monoclonal antibody to the target antigen, or
    - whether there is an absence of any indications that undue experimentation or undue adaption of known core steps would be necessary for preparing a monoclonal antibody;
- whether the scope of an antibody claim in respect to the antigen is appropriate.

Thus, the enablement requirement of paragraph 27(3)(*b*) of the *Patent Act* is satisfied in cases where a person skilled in the art, in view of their common general knowledge and having only the specification and the fully characterized antigen, would be enabled to produce a monoclonal antibody specific to that antigen without displaying inventive ingenuity or undertaking undue experimentation.

A specification must not only be enabling with respect to a claimed monoclonal antibody but also must provide a correct and full description of the antibody to satisfy paragraph 27(3)(*a*) of the *Patent Act*.

Although each application will be considered on its own merits, the following non-exhaustive list of factors should be considered by examiners when determining whether a specification provides a **correct and full description** of a monoclonal antibody:

- whether there was a full characterization of the target antigen to which the monoclonal antibody specifically binds;
- if not, whether the applicant actually prepared the monoclonal antibody and provided a full characterization thereof;
- if not, whether the applicant prepared a monoclonal antibody and deposited a hybridoma which produces the antibody, in accordance with the *Patent Rules,* on or before the filing date of the application [see 17.06]; and
- whether the scope of an antibody claim with respect to the antigen is appropriate.

As outlined above, paragraph 27(3)(*a*) may be satisfied in respect of monoclonal antibodies described through reference to the fully characterized antigen to which they specifically bind..[3] Depending on the facts of the particular case, a full characterization of the antigen can entail a disclosure of its structure, formula, chemical name, or physical properties. In many cases, the disclosure of the complete amino acid sequence of an antigenic polypeptide may indicate possession of all the putative epitopes carried by the polypeptide and, by extension, serve to correctly and fully describe the genus of the corresponding generic monoclonal antibodies..[4]

Cases in which more detailed support may be required to provide a full characterization of the antibody invention include:

- where the applicant is claiming a particular monoclonal antibody reciting particular functional characteristics that go beyond the simple interaction with the target antigen binding, e.g., where the monoclonal antibody is asserted to have agonist, antagonist or neutralizing activity, specificity for a particular epitope, or a remarkably high affinity constant;.[5]
- the target antigen is complex;
- despite the target antigen being novel, the full characterization of the antigen identified the presence of substructures or epitopes that are common to a known antigen; and/or
- monoclonal antibodies immunoreactive with the novel target antigen could be either inherently known, by virtue of cross-reactivity with the novel antigen, or obvious..[6]

Depending on the facts of the particular case, this detailed support may come, for example, in the form of a disclosure of a representative embodiment of the antibody, a biological deposit, or an explicit description of the amino acid sequences of the binding regions of the monoclonal antibody, the epitope and/or the binding pocket of the target antigen essential to its function.

17.07.02*b*
Other patentability requirements

In order to be patentable, a claimed monoclonal antibody must be **novel** and **non-obvious** in accordance with sections 28.2 and 28.3 of the *Patent Act*, respectively. Please see Chapter 15 of this manual for a general discussion of anticipation and obviousness.

The Office considers that where the description includes a full characterization of a novel and inventive antigen X, a claim to the corresponding monoclonal antibody having specific binding to X would be novel and non-obvious.

An enabling prior art disclosure of a monoclonal antibody specific to antigen X would anticipate a claim to a generic monoclonal antibody specific to antigen X. In cases where antigen X is disclosed and enabled by the prior art, a claim to a generic monoclonal antibody that binds antigen X would be obvious in view of the prior art. However, a claim to an antibody that binds antigen X may be novel and non-obvious where the claimed antibody is additionally defined in the claim by properties that distinguish the antibody from both generic and prior art antibodies, which may include:

- its structure, i.e., nucleotide or amino acid sequences;
- reference to a novel hybridoma which produces the claimed antibody and which was deposited in accordance with the *Patent Rules* (see 17.06); and/or
- a specific and supported binding activity, such as an affinity that exceeds the threshold affinity that is expected from a generic antibody.

A monoclonal antibody invention must also be **useful** (for further guidance see 17.07.05).

Where an application claims nucleic acids or polypeptides relating to antibodies of the invention (e.g., light and heavy chains, variable regions, CDRs, etc.), the nucleic acids and polypeptides must be fully supported by the description (for further guidance see 17.05).

17.07.02*c*
Examples

The following hypothetical examples are provided to help clarify the foregoing.

Example 1:

An application discloses a novel tyrosine kinase protein, its complete amino acid sequence (SEQ ID NO:2) and corresponding nucleic acid sequence (SEQ ID NO:1). According to the description, enhanced activity of the protein is associated with pulmonary fibrosis. An embodiment of the invention includes monoclonal antibodies that specifically bind and inhibit the protein although no working examples of an antibody are described. A search of the prior art failed to identify any proteins with significant identity over the full length of the amino acid sequence depicted in SEQ ID NO:2 or any corresponding nucleic acid molecules.

Claims:

1. A protein comprising the amino acid sequence of SEQ ID NO:2.
2. A monoclonal antibody which specifically binds to the protein of claim 1.

Analysis: in this case, the examiner determined that claim 1 is compliant with the *Patent Act* and *Rules* (see 17.05 for further guidance on subject-matter related to this claim). The claimed subject-matter is novel and non-obvious because the prior art does not disclose or suggest any protein having an amino acid sequence with significant identity to SEQ ID NO:2. Further, the matter is fully supported by a specification that satisfies subsection 27(3) of the *Patent Act* because the specification is enabling with respect to preparing the protein and includes a full characterization of this protein (i.e., through the disclosure of its complete amino acid sequence). The claim also complies with subsection 27(4) of the Act as the subject-matter is distinctly and explicitly defined.

Regarding claim 2, novelty and inventiveness is acknowledged because the antigenic target of the claimed monoclonal antibody (i.e., the protein of SEQ ID NO:2) is novel and non-obvious. The scope of claim 2 in respect of the antigenic target is limited to the fully characterized protein of SEQ ID NO:2 and the examiner considers that this provides a correct and full description of the corresponding claimed monoclonal antibodies. In this case, the person skilled in the art is also enabled to produce the monoclonal antibody at the filing date of the application. Therefore, the claimed monoclonal antibody is fully supported by a specification that satisfies subsection 27(3) of the *Patent Act*. The claim also complies with subsection 27(4) of the Act as the subject-matter is distinctly and explicitly defined.

Example 2:

The description discloses the production of murine monoclonal antibody, M1, specific for the RF protein for use in diagnosing Rheumatoid arthritis. Also disclosed are details of a biological deposit of the hybridoma that produces the antibody. A further embodiment includes monoclonal antibodies that compete with M1 although a working example of competing antibodies is not disclosed. A search of the prior art identified the murine RF protein and its full amino acid sequence.

Claims:

> 1. An antibody selected from an anti-RF monoclonal antibody and an antigen-binding fragment thereof.
>
> 2. A monoclonal antibody that specifically binds to RF wherein the antibody is produced by the hybridoma having accession number IDAC 022612-11.
>
> 3. An antibody that competes for specific binding to RF with monoclonal antibody M1 produced by the hybridoma having accession number IDAC 022612-11.
>
> 4. An isolated polynucleotide encoding the variable light chain or heavy chain of the antibody of claim 2.

Analysis: claim 1 is obvious. The scope of the claim encompasses any monoclonal antibody that is specific to the antigenic RF protein. Given that techniques for preparing monoclonal antibodies were well established as of the claim date of the application, in this case, no inventive ingenuity is required on the part of the person skilled in the art to prepare a monoclonal antibody, or antigen-binding fragment thereof, with specific binding to the known RF protein. Therefore, the claim is not in accordance with section 28.3 of the *Patent Act*. It is noted that the subject-matter of the claim is otherwise novel, defined in distinct and explicit terms and supported by a specification that satisfies subsection 27(3) of the Act. The scope of claim 1 in respect of the target antigen is limited to the known and fully characterized antigenic RF protein and the examiner considers that this provides a correct and full description of the corresponding monoclonal antibodies and fragments thereof. In this case, the person skilled in the art, in view of their common general knowledge of routine antibody methods and having only the specification and the fully characterized antigen, would be enabled to produce an antibody (and fragments thereof) specific to RF without displaying inventive ingenuity or undertaking undue experimentation.

Claim 2 defines the antibody by reference to a deposit of the hybridoma that produces it. The claim is novel since the prior art does not describe or enable the antibody (or antigen-binding fragment thereof) obtained from the hybridoma and is non-obvious because, unlike claim 1 to a generic antibody, claim 2 is limited to the particular antibody produced by the hybridoma having accession number IDAC 022612-11. Further, claim 2 is supported by a specification that satisfies subsection 27(3) of the *Patent Act* because it is enabling with respect to the particular antibody claimed and, assuming that the hybridoma which produces M1 was deposited in accordance with the *Patent Rules*, the provision of the deposited hybridoma serves to provide a correct and full description of the M1 antibody. Therefore, the claim fully complies with the *Patent Act* and *Rules*.

In claim 3, the antibody is distinctly and explicitly defined as one that competes with monoclonal antibody M1 for specific binding to the RF protein and, thus, satisfies subsection 27(4) of the Act. As noted above, the M1 antibody produced by the hybridoma having accession number IDAC 022612-11 is novel and non-obvious and it follows that an antibody that competes for specific binding with that particular antibody is also novel and non-obvious. Appreciating that the person skilled in the art could identify competing antibodies without undertaking undue experimentation or the need to exercise inventive ingenuity (e.g., by using routine competition binding assays), the subject-matter of claim 3 is enabled. Assuming that the hybridoma which produces M1 was deposited in accordance with the *Patent Rules*, the provision of the deposited hybridoma serves to provide a correct and full description of the M1 antibody and antibodies in general that specifically bind the same epitope, i.e., competing antibodies. Therefore, the claim is supported by a specification that satisfies subsection 27(3) of the *Patent Act* and complies fully with the *Patent Act* and *Rules*.

Claim 4 is not compliant with the *Patent Act* and *Rules*. The description discloses details of a biological deposit of the hybridoma that produces the antibody but does not disclose the full nucleotide or amino acid sequences of the antibody itself. Therefore, the polynucleotide of claim 4 lacks compliance with paragraph 27(3)(*a*) of the Act. It is noted that a deposit of biological material is not a substitute for a full and correct description of the polynucleotide molecule itself (see 17.06.01 for further guidance). Further, the claim lacks compliance with subsection 27(4) of the Act because the polynucleotide is not distinctly and explicitly defined in the claim.

17.07.03
Humanized and chimeric monoclonal antibodies – January 2017

Advances in genetic engineering techniques have permitted the production of therapeutic humanized and chimeric monoclonal antibodies that combine non-human (e.g., mouse) and human amino acid sequences. The antibodies retain the non-human antigen binding characteristics conferred by the non-human sequences but beneficially elicit less antibody immunogenicity in human recipients as compared to a fully non-human monoclonal antibody.

A humanized monoclonal antibody is a "CDR-grafted" antibody meaning that only the non-human complementarity determining regions (CDRs) of the variable light and heavy chains and selected variable region framework residues have been transferred or "grafted" onto a human antibody template.

A chimeric monoclonal antibody is considered by the person skilled in the art to be a monoclonal antibody in which the non-human constant regions have been replaced with human constant regions. Chimeric antibodies are generally understood to exclude CDR-grafted antibodies.

A determination of whether a specification complies with subsection 27(3) of the Act in relation to humanized and chimeric monoclonal antibodies will generally rely on the same considerations as for monoclonal antibodies (see 17.07.02a).

Recall that compliance with paragraph 27(3)(*b*) of the Act requires the person skilled in the art to be enabled to make or use the antibody invention. Although core steps for preparing humanized and chimeric antibodies are now well established in the state of the art, the examiner must carefully consider, on a case-by-case basis, whether the skilled person, in view of their common general knowledge in the relevant art and the teachings of the specification, was enabled to prepare a humanized or chimeric antibody specific for the target antigen without having to undertake undue experimentation or display inventive ingenuity at the filing date.

Thus, paragraph 27(3)(*b*) may be satisfied in cases where, at the filing date, a person skilled in the art, in view of their common general knowledge and having only the specification and a fully characterized target antigen would not have to undertake undue experimentation or display inventive ingenuity to produce a generic humanized or chimeric monoclonal antibody specific to the target antigen.

Recall also that in order to satisfy paragraph 27(3)(*a*) of the Act, the specification must correctly and fully describe the antibody invention. When determining whether a humanized or chimeric antibody is correctly and fully described, the examiner may rely on the same considerations as for monoclonal antibodies as outlined in 17.07.02*a*. In brief, depending on the facts surrounding a particular case, a humanized or chimeric antibody may be correctly and fully described through reference to, for example:

- the fully characterized antigen to which the antibody specifically binds (e.g., the complete amino acid sequence of the target antigenic protein);
- a structural description of the humanized or chimeric antibody (i.e., the nucleotide or amino acid sequences which minimally encompass the non-human CDRs or the specific monoclonal antibody from which the antibody is derived);
- a hybridoma that produces the monoclonal antibody from which the humanized or chimeric antibody is derived and which was deposited in accordance with the *Patent Rules* on or before the filing date of the application [see 17.06]; or
- a structural description of the epitope to which the humanized or chimeric antibody binds.

In some cases a correct and full description of a claimed humanized or chimeric antibody may require more detailed support (see 17.07.02*a*).

Even where subsection 27(3) of the Act is satisfied, a claim to a humanized or chimeric antibody may not be patentable if the antibody lacks novelty or inventiveness. For instance, a claim to a generic humanized monoclonal antibody may be anticipated and/or obvious in view of an enabling prior art disclosure of: the fully characterized antigenic target to which the claimed antibody binds; monoclonal antibodies (including humanized or chimeric monoclonal antibodies) specific to the same antigenic target; or nucleotide or amino acid sequences corresponding to the CDRs of the claimed antibody.

A humanized or chimeric monoclonal antibody invention must also be **useful** (for further guidance see 17.07.05).

Example:

An application discloses a Sonic Hedgehog (Shh) protein homolog and its complete amino acid sequence (SEQ ID NO:2). According to a working example in the description, a murine monoclonal antibody was prepared using conventional methods and was shown to have high affinity to the homolog *in vitro* with no cross-reactivity to other Shh proteins. The specification does not include any details of either the structure of the antibody or any hybridoma clone. The description further states that the invention encompasses antibodies specific to the Shh homolog including polyclonal, monoclonal, chimeric and humanized antibodies as well as antigen binding fragments (Fab, Fab',

$F(ab')_2$, scFV and diabodies), which can be obtained using routine techniques known to persons skilled in the art.

Claim:

> 1. An isolated antibody or antibody fragment thereof that specifically binds to a Sonic Hedgehog protein homolog comprising the amino acid sequence of SEQ ID NO:2, wherein the antibody or antibody fragment thereof is selected from the group consisting of polyclonal, Fab, Fab', $F(ab')_2$, monoclonal, chimeric, scFV, diabody and humanized.

Analysis: claim 1 encompasses polyclonal antibodies, monoclonal antibodies, chimeric monoclonal antibodies, humanized monoclonal antibodies and antibody fragments (Fab, Fab', $F(ab')_2$, scFv or diabody).

With respect to enablement pursuant to paragraph 27(3)(*b)* of the *Patent Act*, all of the antibodies and fragments encompassed by claim 1 are enabled since core methods for preparing these were well known to the person skilled in the art at the filing date of the application. The description also confirms that conventional methods were sufficient to at least make a monoclonal antibody specific to the homolog. A correct and full description of the subject-matter pursuant to paragraph 27(3)(*a)* of the *Patent Act* over the entire scope of claim 1 is provided by virtue of the fully characterized target antigen to which the antibodies and fragments specifically bind. In this case, the complete amino acid sequence (SEQ ID NO:2) serves to fully characterize the antigen, and by extension, the corresponding antibodies and antigen binding fragments thereof.

The examiner also determines that the target antigen is novel, non-obvious and useful and, therefore, the claimed antibodies and antigen binding fragments that specifically bind this antigen are likewise novel, non-obvious and useful. The claim also complies with subsection 27(4) of the Act as the subject-matter is distinctly and explicitly defined.

In view of the above, claim 1 complies with the *Patent Act* and *Rules*.

17.07.04
Fully human monoclonal antibodies – January 2017

Unlike chimeric and humanized monoclonal antibodies (see 17.07.03), human antibodies are derived entirely from human genes and, in view of this, are more desirable for use in therapeutic and diagnostic applications in humans.

A determination of whether a specification complies with subsection 27(3) of the Act in relation to human monoclonal antibodies will generally rely on the same considerations as for monoclonal antibodies (see 17.07.02*a*).

Recall that compliance with paragraph 27(3)(*b*) of the Act requires the person skilled in the art to be enabled to make or use the antibody invention. Although core methodologies, such as phage display technologies and transgenic-mouse technologies, are now routinely practised by persons skilled in the art to prepare fully human monoclonal antibodies to desired antigenic targets, the examiner must carefully consider, on a case-by-case basis, whether the skilled person, in view of their common general knowledge in the relevant art and the teachings of the specification, was enabled to prepare an antibody without having to undertake undue experimentation or display inventive ingenuity at the filing date. See also 17.07.02*a*.

Thus, the enablement requirement of paragraph 27(3)(*b*) of the *Patent Act* is satisfied in cases where a person skilled in the art, in view of their common general knowledge and having only the specification and the fully characterized antigen would be enabled to produce the antibody specific to that antigen without displaying inventive ingenuity or undertaking undue experimentation.

Recall also that in order to satisfy paragraph 27(3)(*a*) of the Act, the specification must correctly and fully describe the antibody invention. When determining whether a human monoclonal antibody is correctly and fully described, the examiner may rely on the same considerations as for monoclonal antibodies as outlined in 17.07.02*a*.

Even where subsection 27(3) of the Act is satisfied, a claim to a human monoclonal antibody may not be patentable if the antibody lacks novelty or inventiveness. For instance, a claim to a generic human monoclonal antibody may be anticipated by an enabling prior art disclosure, or may be obvious in view of an enabling prior art disclosure of: the fully characterized antigenic target to which the claimed antibody binds; monoclonal antibodies specific to the same antigenic target; or nucleotide or amino acid sequences corresponding to the CDRs of the claimed antibody.

A human monoclonal antibody invention must also be **useful** (for further guidance see 17.07.05).

17.07.05
Antibodies and utility – November 2017

An antibody invention must also be useful in order to satisfy section 2 of the *Patent Act*. The utility does not need to be expressly set out in the specification; however, if the invention's utility is questioned, utility must be demonstrated or soundly predicted as of the application's filing date. The threshold that must be proven to establish utility is generally quite low;.[7] a "mere scintilla" of utility will suffice..[8]

The skilled person in the art would generally accept that if an antigen itself has a practical utility then antibodies that bind the antigen would have at least some utility (e.g., for *in vitro* applications such as immunohistochemistry, flow cytometry and Western blotting). Where the subject-matter of the invention is directed to an antibody that is useful for an *in vivo* therapeutic application, the therapeutic utility would need to be either demonstrated or soundly predicted in order to satisfy section 2 of the *Patent Act*.

In cases where the utility requires the antibody to possess not only binding capacity to the target antigen but also functional activities, such as antagonist (i.e., blocking), agonist (i.e., activating) or neutralizing activity, the description would likely require more than a disclosure of the binding capacity to the target antigen to establish utility. The provision of a working example of the claimed antibody and *in vitro* or *in vivo* data showing the antibody has the required activity may be sufficient to demonstrate utility. In the absence of demonstration, the applicant must be in a position to soundly predict the additional functional activity necessary for the utility.

17.07.06* (formerly 17.07.02a)
Provisos and utility – January 2009

Where a proviso has been presented to avoid inoperative subject-matter, the basis upon which the utility of the remaining matter of the claim has been established must be reconsidered. Since utility will often be based on a sound prediction, a proviso to exclude a known inoperative embodiment requires that the line of reasoning upon which the utility of the remaining matter of the claim is based be reassessed.

17.07.07* (formerly 17.07.05)

Scope of claims – January 2009

In order to fulfill their public notice function, a claim must define the invention in such a manner that the person skilled in the art will understand where they may and may not go without infringing.

As Lord Loreburn noted in *Natural Kinematograph Co v Bioschemes Ltd*, "[t]he patent system is designed to advance research and development and to encourage broader economic activity. Achievement of these objectives is undermined however if competitors fear to tread in the vicinity of the patent because its scope lacks a reasonable measure of precision and certainty. A patent of uncertain scope becomes a public nuisance"..[9]

An objection to a claim for ambiguity or lack of clarity as to its limits (indefiniteness) is made under subsection 27(4) of the *Patent Act*. A claim is not indefinite simply because it is broad, but rather where the precise limits of the claim are uncertain. A claim that relies, for example, on the use of "a polyol" is not indefinite since the person skilled in the art can immediately appreciate the scope of that term. A claim relying on "a polyol capable of <performing some function>", however, is indefinite if the person skilled in the art would not know, or be able to reasonably predict or determine, what polyols fall within the scope of the claim.

17.07.07*a** (formerly 17.07.05*a*)

Recourse to the description

During examination, the language of the claims is interpreted by giving each term its plain and usual meaning in the art to which the invention pertains unless it is clear from the description that a term in the claims is to be given a different meaning.

The courts have acknowledged that an applicant can act as their own lexicographer, by specifying in their description that certain terms will have particular meanings for the purposes of the application. Whenever an applicant is desiring to act as their own lexicographer, however, it is incumbent on them to make this clear from the language of the description. Further, in so acting it is not proper to give a term having a well-known meaning a definition which is contrary to this meaning. In such cases, uncertainty exists as to whether the term, when found in a claim, is intended to have its usual or distorted meaning.

For example, teaching that the term "up" means "down" for the purposes of the invention is only liable to cause confusion and serves no purpose. Such a definition, when made in the description, would be objected to under subsection 27(3) of the *Patent Act*. Further, the claim containing the term "up" is objected to under subsection 27(4) of the *Patent Act* for the lack of clarity as to whether the term is intended to actually mean "up", or rather to mean "down" following the teachings of the description. Similarly, teaching that the symbol "P" indicates nitrogen atoms is misleading; the symbol is recognized in chemistry as designating phosphorus, and could readily be replaced by the appropriate symbol "N" to designate nitrogen. In contrast, teaching that the term "protein", for the purposes of the invention, has some specific but sensible meaning could be acceptable, especially where this avoids having to repeatedly include a lengthy definition in the claims.

Whenever inclusion of the definition found in the description into the claims would not be detrimental to the clarity and conciseness of the claim, however, this should be done.

It is worth noting that the courts, in construing the claims of a patent, are dealing with a document whose language is fixed. Any deficiencies in the language of the claim can only be remedied by construing the claim in "an informed and purposive way". During examination, in contrast, the language of the claims may be amended so as to remove ambiguity and maximize their usefulness in serving their public notice function of defining the extent of the monopoly sought..[10]

Where a defect of clarity has been noted by an examiner in the language of a claim, it will generally be maintained in the face of a response arguing that the courts could, with the assistance of expert testimony, arrive at some construction thereof. The purpose of the claims is to serve a public notice function, and "nothing can excuse the use of ambiguous language when simple language can easily be employed"..[11]

17.08

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17.09

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17.10
Synergistic chemical combinations – March 2016

The Office considers a synergistic combination to be one in which the combined use of two or more compounds or products generates a result that is greater than the sum of its parts and provides an unexpected advantage..[1] Please see Chapters 9 and 11 of this manual for a general discussion of combinations.

Generally, implementing the physical acts of mixing or physically combining different chemical compounds or products does not require inventive activity; however, an inventive step may be acknowledged for a synergistic combination of known components that leads to an unexpected advantage (i.e., the synergistic effect) provided the advantage was disclosed in the originally filed description..[2]

To ascertain whether an unexpected advantage has been produced by a combination, it is necessary to be aware of the point of reference (the result to be expected from combining the individual components), either in view of the common general knowledge of the person skilled in the art in the relevant field or in view of the description.

The utility of a chemical combination is typically closely associated with the unexpected advantage. The utility of the combination must be established at or before the filing date of the application over the entire scope of the claim. Thus, where a synergistic effect is explicitly promised in an application, the synergistic effect must be either demonstrated or soundly predicted in order to establish utility.

In cases where a first compound has been applied to its known purpose and another compound in the combination unexpectedly enhances the result of the first compound, the enhancement effect is, in some fields, referred to as potentiation and requires similar considerations to those described above with regard to patentability.

17.11
Reach-through claims – March 2016

A “reach-through” claim seeks to encompass subject-matter extending beyond the described invention in cases where the matter has not yet been identified by the inventor but may be discovered through future use of the invention. Considering that “nothing that has not been described may be validly claimed”,.[1] in a reach-through claim the subject-matter defined by the claim is not supported by the specification since the specification fails to provide an adequate written description of the matter.

> To illustrate, consider an invention featuring a novel and inventive protein associated with disease Y. Claims to the protein and a method of screening for drugs that inhibit the protein may be acceptable; however, a claim to a product defined by the screening method, e.g. "a drug identified by the method of claim 2" would be considered a reach-through claim where products of the method have not yet been identified. In effect, the claim to a product identified by the method attempts to "reach through" the method in order to define a product that could be potentially identified in the future. Therefore, unidentified products of the method cannot be claimed as such a claim would fail to satisfy section 84 of the *Patent Rules*. Furthermore, where a product is claimed and not properly described in the specification, the disclosure and enablement requirements of subsection 27(3) of the *Patent Act* cannot be satisfied.

As a further example, consider an invention directed to a new and inventive method of identifying receptor ligand antagonists. Although such a method may be patent-eligible, the method cannot be legitimately extended to generally claim all antagonists which might eventually be discovered through the future use of the inventive method. Likewise, the subsequent use of these unidentified antagonists, e.g. to treat disease, would not be patentable.

Thus, examples of reach-through claims may include:

- product claims directed to *unidentified* substances defined solely in terms of either the process or method used to identify them or by their ability to modulate the biological function of a biomolecule (e.g., antagonists and agonists); and
- process, method or use claims that use said *unidentified* substances.

Appendix 1
Deposits of biological material – March 2016

For the purposes of section 38.1 of the *Patent Act*, the term "biological material" includes material which is capable of direct or indirect self-replication. Directly self-replicating biological materials are those that replicate by themselves. Indirectly self-replicating biological materials are those that are capable of replication only in association with a directly self-replicating biological material. Bacteria, fungi (including yeast), plant seeds, cells in culture and hybridomas are representative examples of directly self-replicating materials; indirectly self-replicating materials include nucleotide sequences, plasmids, vectors, viruses, phages and replication-defective cells.

The Budapest Treaty

The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (The Budapest Treaty) was established in 1977. The Treaty is administered by WIPO and obliges contracting states to recognize the fact and date of a deposit of biological material for patent purposes, when it is made in a depositary which has acquired official status under the Treaty. Such a depositary is known as an International Depositary Authority (IDA). An applicant who is making multiple patent filings need only make one IDA deposit to satisfy the deposit practice in all contracting states.

The term "microorganism" is not defined in the Treaty so that it may be interpreted in abroad sense as to the applicability of the Treaty to microorganisms to be deposited under it. Whether an entity technically is or is not a microorganism matters less in practice than whether deposit of that entity is necessary for the purposes of disclosure and whether an IDA will accept it. Thus, for example, tissue cultures, plant seeds and plasmids can be deposited under the terms of the Treaty, even though they are not microorganisms in the strict sense of the word.

The *Budapest Treaty* came into force, with respect to Canada, on September 21, 1996.

Where to make a deposit

A list of International Depositary Authorities and their specific requirements is available at the WIPO website.

When to make a deposit

In accordance with subsection 104(1) of the *Patent Rules*, a deposit of biological material with an international depositary authority must be made on or before the filing date of the application.

Identifying a deposit

In accordance with subsections 104(2) and 104(3) of the *Patent Rules*, the applicant must inform the Commissioner, prior to publication of the application, of the name of the IDA and the accession number given by the IDA to the deposit, and must include that information in the description. Further, in accordance with section 104.1 of the *Patent Rules*, the applicant must include in the description the date of the original deposit with the IDA.

Term of deposit

When a sample of biological material is deposited in an IDA under the *Budapest Treaty* for the purposes of patent protection, the depositor undertakes not to withdraw the sample for a period of at least 30 years from the date of deposit and for at least five years from the date of the most recent request made to the depositary for the furnishing of a sample of the deposited material (Rules 6 and 9 of the Regulations under the *Budapest Treaty*).

New and substitute deposits

After an original sample of biological material has been deposited in an IDA (an original IDA deposit), circumstances may necessitate that a new sample of the same material be deposited in either the same or a different IDA (Article 4 of the *Budapest Treaty*) or that the sample be transferred to a substitute IDA (Rule 5 of the *Regulations Under the Budapest Treaty*).

If an IDA cannot furnish a sample of deposited material because it is no longer viable, a depositor must make a new deposit in the same IDA.

If an IDA cannot furnish a sample of deposited material because the sample must be sent abroad and this is prevented by export or import restrictions, a depositor may make a new deposit in another IDA.

To maintain an original IDA deposit date, a new deposit must be made within three months of the depositor receiving notice from an IDA that a sample is no longer viable or cannot be sent abroad, or that the IDA's status has changed. The deposit must be accompanied by a statement that the newly deposited material is the same as that originally deposited. Under subsection 106(2) of the *Patent Rules*, if a new deposit is not made in accordance with Article 4 of the *Budapest Treaty*, the application is treated as if no deposit had ever been made.

If an IDA temporarily or permanently discontinues any of the tasks required of it as an IDA such that samples of deposited biological material can no longer be provided, the defaulting IDA is required to transfer samples of deposited materials to another IDA. The new IDA is referred to as a substitute IDA and the deposit is known as a substitute deposit.
In accordance with section 105 and subsection 106(1) of the *Patent Rules*, whenever a deposit of a biological material is made (or transferred) to an IDA different from the original IDA, the applicant must inform the Commissioner of the name of the new IDA and of the accession number given by the new IDA to the deposit before the expiry of the three-month period after the date of issuance of a receipt by that IDA.

Access to deposited biological material

Deposited biological material becomes available to the public once a patent application is open to inspection under section 10 of the *Patent Act,* or for applications filed before October 1, 1989 once a patent issues.

In accordance with subsection 104(4) of the *Patent Rules*, an applicant is entitled to restrict access to a deposit of biological material until such time as a patent has issued, or the application is refused, abandoned and no longer subject to reinstatement, or withdrawn, provided that they file a notice with the Commissioner before the application is open to public inspection. In such cases, any person may request that an independent expert be nominated by the Commissioner in accordance with subsection 109(1) of the *Patent Rules*. Once so nominated, that expert will have access to the deposit in accordance with subsection 104(4) of the *Patent Rules*.

In order to access a deposited biological material, a request must be made. Where a restriction has been made by the applicant and is in effect, only the independent expert may make such a request. When such a restriction is not in place, or no longer applicable, any person may request access to the deposited material.

A request for a sample of the biological material must be submitted to the Commissioner of Patents and requires, *inter alia*, that the requester undertake in accordance with section 108 of the *Patent Rules* not to make the sample, or any culture derived from the sample, available to any other person nor to use the sample, or any culture derived from the sample, for any purpose other than experiments that relate to the subject-matter of the application until such time as a patent issues, or the application is refused, abandoned and no longer subject to reinstatement, or withdrawn.

In the case of a granted patent, the request for a sample of the deposited material may be made directly to the IDA, without the need to provide a request form certified by the Commissioner of Patents unless the IDA specifically requires that a certified request form indicating that the patent has been issued be submitted.

A request form for the furnishing of a sample of deposited material will be published from time to time in the Canadian Patent Office Record (CPOR) and is also provided as Appendix 3 of the *Guide to the Deposit of Microorganisms under the Budapest Treaty* which may be found on the WIPO website.

Detailed procedures for obtaining samples of biological materials are provided in Appendix 2.

Nomination of an independent expert

In accordance with subsection 109(1) of the *Patent Rules*, the Commissioner of Patents will nominate an independent expert with the agreement of the applicant. Both the applicant and the person requesting that an expert be nominated may make suggestions as to who would be a suitable expert. In the event that the Commissioner of Patents and the applicant cannot agree on an acceptable expert within a reasonable time after a request has been made that such an expert be nominated, the applicant's notice under subsection 104(4) of the *Patent Rules* that access to a deposit be restricted to an expert is deemed, in accordance with subsection 109(2) of the *Patent Rules*, never to have been filed.

Certification

After a request has been filed with the Commissioner of Patents for the furnishing of a sample of deposited biological material, the Commissioner will, in accordance with subsection 107(2) of the *Patent Rules*, make the certification referred to in Rule 11.3(a) of the *Regulations Under the Budapest Treaty* that the deposit is referred to in an application for patent in Canada, that the requester has fulfilled all conditions for the furnishing of a sample, and that the requester has a right to a sample of the deposited material.

A copy of the request along with the certification is then sent to the requester in accordance with subsection 107(3) of the *Patent Rules* or in the case where the requester is an independent expert, to the applicant and to the person who requested the nomination of the expert in accordance with subsection 110(2) of the *Patent Rules*.

Appendix 2

Steps for obtaining samples of biological materials – March 2016

To obtain a sample of a biological material referred to in a pending application on which no restriction has been placed under subsection 104(4) or 160(4) of the *Patent Rules*:

(i) the requesting party completes parts I through IV of the request form;

(ii) the requesting party prepares a letter of undertaking, agreeing to abide by the conditions set out in section 108 or 164 of the *Patent Rules*;

(iii) the requesting party, under a covering letter, sends the letter of undertaking and the request form to the Commissioner of Patents, Place du Portage I, 50 Victoria St., Gatineau, Canada, K1A 0C9;

(iv) the Commissioner, or a designate, completes part V of the request form, certifies it with the seal of the Patent Office and returns it to the requesting party under a covering letter;

(v) the requesting party sends the request form, a purchase order and any fee required to the IDA;

(vi) the IDA sends a sample of the biological material to the requesting party.

To release a sample of a biological material referred to in a pending application, on which a restriction has been placed under subsection 104(4) or 160(4) of the *Patent Rules,* to an independent expert:

(i) the requesting party requests that the Commissioner of Patents nominate an independent expert for the purposes of the application;

(ii) the Commissioner of Patents, with the agreement of the applicant, nominates an independent expert within a reasonable time;

(iii) the independent expert completes parts I through IV of the request form;

(iv) the independent expert prepares a letter of undertaking, agreeing to abide by the conditions set out in section 108 or 164 of the *Patent Rules*;

(v) the independent expert, under a covering letter, sends the letter of undertaking and the request form to the Commissioner of Patents, Place du Portage I, 50 Victoria St., Gatineau, Canada, K1A 0C9;

(vi) the Commissioner, or a designate, completes part V of the request form, and certifies it with the seal of the Patent Office;

(vii) the Commissioner sends, under covering letters, the completed request form to the requesting party, and a copy of thereof to the applicant;

(viii) the requesting party sends the request form, a purchase order and any fee required to the IDA;

(ix) the IDA sends a sample of the biological material to the independent expert.

To obtain a sample of a biological material referred to in an issued patent:

(i) the requesting party writes to the IDA with a purchase order giving the name and address of the requesting party;

(ii) the order should include evidence, e.g., a copy of the cover page of the Canadian patent, indicating that the patent has issued and the accession number of the biological material desired;

(iii) where required, the fee charged by the IDA for furnishing the sample is submitted along with the order.

Endnotes for Chapter 17

Endnotes for 17.01

1. United Nations Convention on Biological Diversity, Article 2. Use of Terms, 1992 [(http://www.cbd.int/convention/text/); retrieved: 31 October 2011]

Endnotes for 17.02

1. Harvard College v. Canada (Commissioner of Patents), 2002 SCC 76; [(2002), 21 C.P.R. (4th), 417 (S.C.C.)] at paragraphs 197-199

2. Re Application of Abitibi Co. [(1982) C.D. 933, 62 C.P.R. (2nd), 81 (P.A.B.)]

3. Harvard (supra at 1) at paragraphs 153-166

4. For the purposes herein, a totipotent stem cell is defined as a cell capable of giving rise to all types of differentiated cells found in an organism, as well as the supporting extra-embryonic structures of the placenta. A single totipotent cell could, by division in utero, reproduce the whole organism. This definition is adopted from that provided in the Glossary on the National Institutes of Health, Stem Cell Information website, https://stemcells.nih.gov/ , retrieved November 2014

5. For the purposes herein, embryonic stem cells are defined as primitive (undifferentiated) cells that are derived from preimplantation-stage embryos, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. Multipotent cells have the ability to develop into more than one cell type of the body. Pluripotent stem cells are capable of differentiating into all tissues of an organism, but are not alone capable of sustaining full organismal development. These definitions are adopted from those provided in the Glossary on the National Institutes of Health Stem Cell Information website, https://stemcells.nih.gov/, retrieved November 2014

6. Monsanto Canada Inc. v. Schmeiser, 2004 SCC 34; [(2004), 31 C.P.R. (4th), 161 (S.C.C.)] at paragraph 17

7. Re Application No. 2,306,317 of L'Oréal [(2011) C.D. 1312, 94 C.P.R. (4th) 274 (P.A.B.)]

8. Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents), [1989] 1 S.C.R. 1623 [(1989), 25 C.P.R. (3rd), 257(S.C.C.)] at pages 263-265 (cited to C.P.R.)

Endnotes for 17.03

1. Tennessee Eastman v. Commissioner of Patents [(1972), 8 C.P.R. (2nd), 203 (S.C.C.)]; Imperial Chemical Industries Ltd. v. Commissioner of Patents [(1986), 9 C.P.R. (3rd), 289 (F.C.A.)]

2. This conclusion is inferred from the decision in Re Application 319,105 of Boehringer Mannheim G.m.b.H. (1987) C.D. 1108, allowing a diagnostic method involving the removal of blood from the body

3. Re Application 394,006 of Catheter Technology Corporation (1986) C.D. 1082

4. Re Application No. 532,566 of General Hospital Corporation (1996) C.D. 1209; Re Application No. 559,960 of Senentek (1997) C.D. 1213

5. Re Application No. 003,389 of N.V. Organon [(1973) C.D. 144, 15 C.P.R. (2nd), 253 (P.A.B.)]; Re Application for Patent of Goldenberg [(1988) C.D. 1119, 22 C.P.R. (3rd), 159 (P.A.B.)]

6. Re Application No. 862,758 (1970) C.D. 33; Re Application No. 954,851 of Biehl (1971) C.D. 63

7. Axcan Pharma Inc. v. Pharmascience Inc., [2006] FC 527 [(2006), 50 C.P.R. (4th), 321 (F.C.)]

8. Re Application No. 003,772 of Ijzerman (1975) C.D. 254; Merck & Co. v. Apotex Inc. [2005] FC 755 [(2005), 41 C.P.R. (4th), 35 (F.C.)]

9. Goldenberg (supra at 5)

10. The term “analyte” is used broadly herein to mean a chemical substance or biomarker that is the subject of analysis.

11. *AstraZeneca Canada Inc. v. Apotex Inc.*, 2010 FC 714 at paragraph 33; *Wenzel Downhole Tools Ltd. v National-Oilwell Canada Ltd.*, 2011 FC 1323 at paragraph 61; *Jay-Lor International Inc. v. Penta Farm Systems Ltd.*, 2007 FC 358 at paragraph 55; *Sanofi-Aventis Canada Inc. v. Apotex*, 2009 FC 676 at paragraph 128; *Merck & Co. Inc. v. Apotex Inc.*, 2010 FC 1265 at paragraph 86

12. To better illustrate, consider a situation where the measurement of analyte X had been routinely performed in urine samples (i.e., the measurement of X in urine was CGK to the POSITA) but in the instant application it is apparent that the inventors have instead performed the measurement of X in saliva. Although the means by which X is measured is the same (e.g., chromatography), using a saliva sample instead of a urine sample would not represent the standard sample source for measuring X and thus would be “non-standard to that means”.

13. For example, consider a situation where it was routine to test for the presence of analyte X after exposure to environmental hazard Z (i.e., the measurement of X after exposure to Z was CGK to the POSITA) but in the instant application the testing for analyte X was performed precisely 36-48 hours post-exposure. Although the assay used to detect X is the same, in this case performing the assay within a window of 36-48 hours post-exposure is not routine and thus would be “non-standard to that means”.

Endnotes for 17.04

1. Radio Corporation of America v. Raytheon Manufacturing Co. [(1957), 27 C.P.R. (1st), 1 (Ex.Ct.)] at page 14

2. Minerals Separation North American Corp. v. Noranda Mines, Ltd. [(1947), 12 C.P.R. (1st), 102 (Ex.Ct.)] at page 111; the cited passage has been referred to more recently in, e.g., Baker Petrolite Corp. v. Canwell Enviro-Industries Ltd. [2001]

FCT 889 [(2001), 13 C.P.R. (4th), 193 (F.C.T.D.)] (rev'd on other grounds) and 671905 Alberta Inc. v. Q'Max Solutions Inc. [2001] FCT 888 [(2001), 14 C.P.R. (4th), 129 (F.C.T.D.)] (varied [(2003), 27 C.P.R. (4th), 385 (F.C.A.)]). Minerals Separation was referred to in both Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd. [(1981), 56 C.P.R. (2nd), 145 (S.C.C.)] at page 157 and Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents), [1989] 1 S.C.R. 1623 [(1989), 25 C.P.R. (3rd), 257(S.C.C.)] at page 268 as in a general sense setting out the requirements of a sufficient disclosure.

3. Consolboard (supra at 2) at pages 154 to 155, Dickson J. quoting H.G. Fox from his Canadian Law and Practice Relating to Letters Patent for Inventions [(1969), 4th Ed.]

4 . Consolboard (supra at 2) at page 157

5. Minerals Separation (supra at 2) at page 111; this passage endorsed in Consolboard (supra at 2) at page 157

Endnotes for 17.05

1. Re Application 2,017,025 of Yeda Research and Development Corporation [(2007) C.D. 1273]

2. Reeck, Gerald *et al.*, " 'Homology' in proteins and nucleic acids: A terminology muddle and a way out of it" (1987), 50 Science 667

3. Altschul, S. *et al.*, "Basic Local Alignment Search Tool" (1990), 215 Journal of Molecular Biology 403

4. *Janssen-Ortho Inc. v. Novopharm Limited*, 2006 FC 1234 [(2006), 57 C.P.R. (4th), 6 (F.C.)] at paragraph 99, aff'd 2007 FCA 217 [(2007), 59 C.P.R. (4th), 116 (F.C.A.)]. The requirement of section 28.3 has been variously described by the courts as one of "ingenuity", "inventive ingenuity", "invention", "inventiveness", and "non-obviousness". These terms can be used more or less interchangeably to describe the requirement codified in s.28.3.

5. *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.* 2008 SCC 61 at paragraph 67

Endnotes for 17.06

1. *Minerals Separation North American Corp. v. Noranda Mines, Ltd.* [(1947), 12 C.P.R. (1st), 102 (Ex.Ct.)] at page 111

2. Pioneer Hi-Bred Ltd. v Canada (Commissioner of Patents), 1989 S.C.R. 1623 [(1989), 25 C.P.R. (3rd), 257(s.C.C.)] at page 271

3. Re Application of Abitibi Co. [(1982) C.D. 933, 62 C.P.R. (2nd), 81 (P.A.B.)]; Re Application No. 291,870 of Connaught Laboratories [(1982) C.D. 962]

Endnotes for 17.07

1. Cobalt Pharmaceuticals Company v. Bayer Inc., 2015 FCA 116 at paragraph 67 and Teva Canada Ltd. v. Pfizer Canada Inc., 2012 SCC 60 at paragraph 90

2. Re Application No. 2,451,493 (2016) C.D. 1398 at paragraph 22 citing Novartis Pharmaceuticals Canada Inc. v. Teva Canada Ltd., 2013 FC 283

3. Re Application No. 2,451,493 (2016) C.D. 1398 citing Re Immunex Corporation Patent Application No. 583,988 [(2010) C.D. 1302, 89 C.P.R. (4th) 34 (P.A.B.)] at paragraph 67-68

4. Re Genentech Inc. Patent Application No. 2,407,304 [(2010) C.D. 1307, 92 C.P.R. (4th) 241 (P.A.B.) at paragraph 68]

5. Re Genentech Inc. Patent Application No. 2,407,304 [(2010) C.D. 1307, 92 C.P.R. (4th) 241 (P.A.B.) at paragraph 67]

6. Re Immunex Corporation Patent Application No. 583,988 [(2010) C.D. 1302, 89 C.P.R. (4th) 34 (P.A.B.) at paragraph 69]

7. Apotex Inc. v. Pfizer Canada Inc. 2014 FCA 250 at paragraph 64

8. Apotex (supra at 7) at paragraph 64, citing Eli Lilly Canada Inc. v. Novopharm Limited 2010 FCA 197 at paragraph 76

9. Natural Colour Kinematograph Co. v. Bioschemes Ltd. 32 R.P.C. 256 at page 266; this passage also cited in Minerals Separation North American Corp. v. Noranda Mines, Ltd. [(1952), 15 C.P.R. (1st), 133 (P.C.)]

10. Any such amendment, of course, must not introduce new subject-matter such as to contravene subsection 38.2(2) of the Patent Act.

11. Natural Kinematograph (supra at 9) at page 266. The use of "ambiguous" in this context should be understood in the context of the entire passage, wherein it was earlier stated that a patent is invalid if it relies on "language which, when fairly read, is avoidably obscure or ambiguous".

Endnotes for 17.10

1. *Lundbeck Canada Inc. v. Ratiopharm Inc.,* 2009 FC 1102, 79 C.P.R. (4th) 243 at paragraphs 228-229

2. *Lundbeck Canada Inc.* (supra at 1)

Endnotes for 17.11

1. *Minerals Separation North American Corp* v Noranda Mines Ltd [(1947), 12 C.P.R. (1st), 102 Ex.Ct.)] at page 111

Chapter 18

Protests and filings of prior art prior to grant

18.01 Filings of prior art - May 2014

As per section 34.1 of the *Patent Act*, any person may file prior art with the Commissioner. This prior art can consist of patents, applications for patents open to public inspection and printed publications that the person believes have a bearing on the patentability of any claim in a patent application. Prior art filed under section 34.1 of the *Patent Act* must be accompanied by an explanation of why the art is pertinent.

As per section 10 of the *Patent Rules*, when prior art is received under the provisions of section 34.1 of the *Patent Act*, the provider will be notified that the filing of prior art has been received but will not be informed regarding any resulting action taken. The examiner will not discuss the prosecution of the application with the provider; however the provider has access to the prosecution file of the application at the time the file is opened to public inspection. The prior art is made part of the application file and the applicant is notified that a submission of prior art has been made.

If the application referred to by the person submitting the prior art is a PCT application which has not yet entered the national phase in Canada, the Canadian Patent Office will retain the submission until the date for late national entry in Canada has passed.

18.02 Protests - May 2014

In accordance with section 10 of the *Patent Rules*, any written communication made to the Commissioner with the stated or apparent intention of protesting against the granting of a patent, prior to it being issued, will be acknowledged by the Commissioner. The protestor will not be informed regarding any resulting action taken; however a protestor has access to the prosecution file of the application at the time the file is opened to public inspection.

Protests may develop as a result of public inspection of laid-open applications or via a search request under section 11 of the *Patent Act*. The protestor should identify the Canadian patent application number if possible, or the foreign patent publication number (if a request under section 11 of the *Patent Act* has not returned a pending Canadian application number). Any protest that fails to identify an application by number, inventor or applicant reduces the likelihood of the Patent Office locating the application and therefore reduces the effectiveness of the protest.

When a protest does not identify an application by number, the Patent Office carries out a search to identify the application to which the protest applies. If the application is found, the protest is made part of the application file and the applicant is notified of the protest. As detailed above, the protestor will also be advised of the receipt of the protest in the Patent Office; however, the application number will not be disclosed if this application is not already laid open for public inspection. When a specific application cannot be located (e.g. when the application has not yet been filed at the Patent Office or when there is not enough information in the protest to identify the application), the Patent Office will retain the protest for two years during which time the Office will continue to attempt to identify the relevant application.

18.03 Applying protests or filings of prior art - May 2014

A protest or a filing of prior art is only considered by the patent examiner after examination of the application has been requested. Information in a protest or a filing of prior art is taken into account by the examiner, and will be used during prosecution if it is found to be pertinent. In the event that a notice of allowance has been sent to the applicant but the patent has not yet issued, the pertinence of the protest or the filing of prior art will determine whether the notice of allowance will be withdrawn. Where the protest or filing of prior art calls the patentability of the application into question, the Notice of Allowance will be withdrawn and the application will be returned to the examiner for further consideration. See chapter 13 for more information on notice of allowance and withdrawal thereof.

A protest may contain affidavits. An affidavit may contain information that could raise serious questions as to whether or not a patent should be granted, or lead to documentation that could be pertinent. A protest containing an affidavit should support any allegations with dated material or give details to help locate such material. Affidavits containing allegations which are not supported by dated documentation will usually be disregarded.

18.04 Confidentiality – June 2016

Any protest or filing of prior art will become part of the laid-open application file and will therefore be made available to the public. Should a party filing a protest or a filing of prior art request that the protest or filing of prior art remain confidential, the protest or filing of prior art will be returned to the sender and will not be considered by the patent examiner. Parties filing a protest or filing of prior art should note that they cannot remain anonymous; information identifying the protestor, such as that provided in the protest or filing of prior art cover letter, will be made available to the public.

Chapter 19
Amendments to patent applications

19.01 Amendments to patent applications

January 2016

Section 38.2(1) of the *Patent Act* states that the specification and any drawings furnished as part of an application may be amended before the patent is issued. An amendment to the specification or drawings may be submitted in response to an examiner's report.

An applicant may also choose to amend the specification or drawings of their own volition; such amendments are known as “voluntary amendments” and are referred to as such in this chapter.

An application that has been amended is subject to further examination to ensure it complies with the *Patent Act* and *Patent Rules*. Any defects identified will be set out in an examiner's report. An amended application may also be subject to a further search of the prior art.

Information regarding amendments to petitions can be found in section 4.01.01 of this manual.

Information regarding clerical error corrections under section 8 of the *Patent Act* or section 35 of the *Patent Rules* can be found in sections 23.04 and 23.05 of this manual.

19.02 Format and requirements for submitting amendments

September 2017

It is strongly recommended that a cover letter be provided with every amendment to help facilitate processing in the Office. The cover letter can be filed in either official language provided that the text matter of the specification and drawings after amendment is wholly in English or wholly in French, as per subsection 71(3) of the *Patent Rules*. Where the applicant submits an amendment or a response following an examiner’s report, any subsequent examiner’s report will be written in the official language used by the applicant in the most recent submission.

It is recommended that one of the following headers in uppercase be used to identify the nature of an amendment, as applicable:

- VOLUNTARY AMENDMENT
- VOLUNTARY AMENDMENT FOLLOWING PCT NATIONAL ENTRY
- AMENDMENT/REMARKS AFTER EXAMINER'S REPORT
- AMENDMENT AFTER ALLOWANCE

New or replacement pages should follow and be separate from the cover letter.

Submissions relating to an application other than amendments to the specification and drawings may be included in the same submission and addressed in the same cover letter. For example, communications regarding an amendment, a submission of prior art, the appointment and/or revocation of an agent, a request for examination, a request for advanced examination ("special order" and applications related to green technology [see chapter 13]) and a request to make a payment of a fee or fees may be incorporated in the same cover letter using uppercase headings.

Where an amendment submission also includes a PPH request form [see chapter 13], this should be mentioned in the cover letter.

It is strongly recommended that all applicable headers be listed in uppercase on the first page of the cover letter. For example:

VOLUNTARY AMENDMENT / AMENDMENT IN RESPONSE TO EXAMINER'S REPORT
SUBMISSION OF PRIOR ART
APPOINTMENT AND REVOCATION OF AGENT
REQUEST FOR EXAMINATION
REQUEST FOR ADVANCED EXAMINATION
MAINTENANCE FEE
PPH REQUEST

An amendment requested to take effect at some time in the future (delayed amendment) is not permitted by the Patent Office. It should also be noted that an examiner will not enter an amendment based upon telephone or email instructions from an applicant.

The following sections set out the requirements that must be met when submitting an amendment.

19.02.01 Identification of the application

As per section 7 of the *Patent Rules*, communications addressed to the Commissioner in relation to an application must include:

- the name of the applicant or inventor;
- the application number, if one has been assigned by the Patent Office; and
- the title of the invention.

It is recommended that the filing date and the classification of the application, if known, be identified in the cover letter. This information is useful to validate the application number.

Subsection 8(1) of the *Patent Rules* requires that communications addressed to the Commissioner in relation to a patent application relate to one application only, subject to the exceptions in subsection 8(2). However, as mentioned above [see 19.02] several action items with respect to one application can be combined in the same communication.

19.02.02 Authentication of the authorized correspondent

Subsection 6(1) of the *Patent Rules* requires that for the purposes of prosecuting or maintaining an application the Commissioner shall only have regard to communications from the authorized correspondent [see 4.02 and 4.03]. The patent agent's signature, the seal or stamp of the firm, or a cover letter with the firm's official letterhead or mark recognized by the Patent Office will be accepted as authentication of the authorized correspondent. When the authorized correspondent is an inventor, assignee, or legal representative, the paper copy of the amendment must be signed, although a copy or an image of the signature on a fax or an electronic image is accepted as authentication.

When an amendment is filed by a person who is not the authorized correspondent on file at the Patent Office, this person or firm will be notified by Office letter that they are not the authorized correspondent and that consequently the amendment cannot be entered. Where a revocation and/or appointment of an agent has recently been submitted to the Office, or is being submitted concurrently with the amendment, the applicant should indicate this in the cover page of the amendment to ensure that the revocation and/or appointment is applied to the file prior to processing the amendment.

19.02.03 Supporting statement

As per section 34 of the *Patent Rules,* an amendment made to an application must be accompanied by a written statement explaining the nature and purpose of the amendment and should include instructions for entering the amendment. This written statement may be included in the cover letter. The instructions provided should be divided by clear headings representing each section of the patent application addressed, such as the description, claims and drawings. Since the applicant may need to address several requisitions made in an examiner's report, it is recommended that distinct headings for each requisition be provided.

19.02.04 Replacement pages and new pages

Generally, when an amendment is received in the Patent Office, it is entered into the application file before an examiner determines whether it complies with the *Patent Act* and *Patent Rules*. If replacement pages are submitted by the applicant they are substituted in place of the pages altered by the amendment (for example if an application contains description pages 1 to 3 and the applicant submits an amended page 2, the existing page 2 will be removed and the replacement page 2 will be entered). If new pages are submitted by the applicant they will be entered (for example if an application contains description pages 1 to 3 and the applicant submits page 2A, page 2A will be entered). The cover letter with the supporting explanation for the amendment is attached to the file. It should be noted that the entry of replacement pages or new pages into the application file does not denote acceptance of the amendment by the examiner.

Where existing pages are being amended, replacement pages must be supplied for all affected pages irrespective of whether the changes are for adding or deleting matter.

All replacement and new pages must meet the criteria of sections 68 to 70 of the *Patent Rules* with respect to documentation presentation.

As per subsection 73(1) of the *Patent Rules*, the pages of the description and claims must be numbered consecutively. Page numbering which includes letters is acceptable; for example the sequence 1, 2, 3, 3A, 3B, 4 is acceptable. If pages are deleted, the applicant should renumber the affected pages to ensure that pages are numbered consecutively; alternatively, the applicant may insert a numbered blank page in place of a deleted page as long as the blank page is marked with a diagonal stroke or a "Z" to indicate that no text is missing and that the space is intended to be left blank. Likewise for deletions which have resulted in partially blank pages, the applicant may insert a "Z" or diagonal stroke to fill areas of empty space to indicate that no text is missing and that the space is intended to be left blank.

Section 85 of the *Patent Rules* requires that claims be numbered consecutively in Arabic numerals.

19.03 New subject-matter

September 2014

According to subsection 38.2(2) of the *Patent Act*, the specification may not be amended to describe subject-matter not reasonably to be inferred from the specification and drawings as originally filed.[i] Similarly, the drawings may not be amended to add matter that is not reasonably to be inferred from the originally filed specification or drawings (subsection 38.2(3) of the *Patent Act*). Matter pertaining to prior art with respect to the invention of the application may be added to the specification and the drawings; however, the applicant must acknowledge in the specification that any such matter is prior art. If an examiner determines that an amended specification or amended drawing comprises new subject-matter, the defect will be identified in an examiner's report and the applicant will be requisitioned to remove the new subject-matter.

Note also that an amendment that results in the removal of subject-matter from the specification or drawings may cause the application to not comply with subsections 38.2(2) or (3) of the *Patent Act*. For example, if the originally filed specification described a component as made of a specific material, an amendment to remove the recitation of that specific material may be considered to describe new subject-matter if it could not reasonably be inferred from the original specification and drawings that the component could be made of material other than that originally stated.

Amendments containing new subject-matter will also be laid open on the date the application is laid open to public inspection or on the date the amendment is placed on file, whichever is later. This could affect the applicant's ability to later successfully obtain a patent in Canada or elsewhere for an invention relying on the new subject-matter.

19.04 Voluntary amendments

September 2014

A voluntary amendment may be made to a patent application at any time during the prosecution of an application; however, examination of such amendments will only be carried out once a request for examination has been received.

A voluntary amendment will be considered to be publicly disclosed on the date the application is laid open to public inspection or on the date the amendment is placed on file, whichever is later. This could have implications for the patentability of any new subject-matter disclosed in the amendment [see section 19.03].

19.05 Amendments to PCT applications

June 2015

Article 19 and 34 amendments made to Patent Cooperation Treaty (PCT) applications during the international phase become part of the national phase application at the time of national entry into Canada as long as such amendments were made *prior* to national entry. After national entry a PCT national phase application is subject to the same amendment requirements as a regularly filed patent application.

Any amendments made during the international phase *after* national entry will not be automatically included in the PCT national phase application. Where an applicant wishes to have such amendments entered into the PCT national phase application, the authorized correspondent must submit them as voluntary amendments.

19.06 Amendments in response to an examiner's report

September 2014

When submitting an amendment in response to an examiner's report identifying defects in an application, the written statement [see 19.02.03] must explain the manner in which the amendment overcomes the defects.

Where an amendment in response to an examiner's report has been submitted by a person who is not the authorized correspondent, the amendment will not be entered [see 19.02.02]. The application will become abandoned if a response to the examiner's report is not submitted by the authorized correspondent before the applicable due date.

The examiner will review the amendment and the written statement and determine whether the amended specification complies with the *Patent Act* and *Patent Rules*. Recognizing that the specification may not be amended to describe matter that is not reasonably inferred from the originally filed specification and drawings, except in cases where the matter is prior art, the examiner will identify such a "new matter" defect, if present, and any additional defects introduced by way of the amendment in a further examiner's report [see 19.03].

Where the applicant believes that the application complies with the *Patent Act* and *Patent Rules* and does not wish to amend the application, arguments must be presented to explain why the applicant thinks that the application is not defective. Paragraph 73(1)(*a*) of the *Patent Act* provides for the abandonment of an application if the applicant does not reply in good faith to any requisition made by an examiner within the prescribed time. A response to an examiner's report will be considered to be not in good faith if:

- The applicant has neither presented an amendment in order to comply with the *Patent Act* and *Rules* nor presented any argument as to why the application does comply. In effect, the applicant has submitted a response that amounts to a non-response; or
- The applicant has responded to a requisition with only clearly false statements.

It should be noted that the Patent Office does not generally requisition the correction of minor errors in a specification such as obvious spelling errors, punctuation and letter inversions (though they may be included in an examiner's report if other defects have been identified). If not corrected, such errors will appear in the granted patent.

19.07 Amendments in response to a *Final Action*

September 2014

Amendments received in response to a *Final Action* are covered in section 21.05.

19.08 Amendments after allowance

January 2016

Subsection 30(1) of the *Patent Rules* specifies that where an examiner has reasonable grounds to believe that the application complies with the *Patent Act* and *Patent Rules*, the Commissioner shall notify the applicant that the application has been found allowable and shall requisition the payment of the applicable Final Fee set out in paragraph 6(*a*) or (*b*) of Schedule II of the *Patent Rules* within the six-month period after the date of the notice.

After a notice of allowance has been mailed but before payment of the final fee, the types of amendments that may be made to an application are limited. Paragraph 32(*a*) of the *Patent Rules* specifies that after the notice of allowance is sent, an application shall not be amended, other than to correct a clerical error that is obvious on the face of the application, unless the fee set out in item 5 of Schedule II of the *Patent Rules* is paid. Paragraph 32(*b*) of the *Patent Rules* states that an application shall not be amended in a way that would necessitate a further search by the examiner in respect of the application or that would make the application not comply with the *Patent Act* or *Patent Rules*.

Examples of corrections to clerical errors include:

- correcting a recognized typographic error within a word (obvious from a dictionary); or,
- inserting a word or group of words which are missing from a sentence, when they are present in other occurrences of this sentence (obvious when considering the whole application).

Note that if a fee was paid in respect to an amendment after allowance, but was not required (i.e., in the case of a clerical error), the fee will not be refunded. For more information on clerical error corrections under section 8 of the *Patent Act* see 23.04 of this manual.

Examples of amendments which are not considered to be corrections to clerical errors include:

- inserting the wording of the broadest independent claim into the description;
- reintroducing elements that were removed previously in response to a report;
- modifications which must be inferred from the application through some effort;
- adding claims of narrower scope or deleting claims or parts of claims; or,
- introducing new description headings.

Where an amendment after allowance fee is required, the examiner will verify that the fee has been paid or that a General Authorization Statement (GAS) for such a fee is included with the amendment. The following language for the GAS statement is recommended:

> "Should the fees submitted with this letter be insufficient to cover all of the fees for which payment is explicitly or implicitly requested by this letter, CIPO is authorized to charge the amount of the insufficiency using one of the payment methods specified on the accompanying Fee Payment Form."

If an amendment after allowance fee is required but was not submitted with the amendment and no GAS for the fee was included with the amendment, the examiner will notify the applicant by letter that the amendment after allowance is refused.

If the required fee was paid or a suitable GAS was provided, the examiner will proceed to examine the amended application. If the amended specification and drawings comply with the *Patent Act* and *Patent Rules* and if the amended specification and drawings do not require a further search of the prior art, the amendment after allowance will be accepted and entered in the application. If the amendment would cause the application not to comply with the *Patent Act* or *Patent Rules*, or if a further search would be required as a result of the amendment, the amendment after allowance will be refused.

An amendment after allowance that broadens the scope of the claims, or changes the point of invention or its characterization so that something additional or different is claimed, will be refused. This includes not only changes to the claims, but also to additions to, or deletions from, the description or drawings which have the effect of broadening the scope of the claims or shifting the point of invention.

If the examiner refuses an amendment after allowance, the applicant will be so advised by the examiner by letter. The letter will indicate the reason(s) for refusal. At this point the applicant may:

- pay the final fee to proceed to issuance with the application in its version before the amendment after allowance; or
- if there is time before the final fee is due, submit arguments as to why the amendment after allowance is acceptable or submit a new amendment after allowance; or
- not pay the final fee, allow the application to become abandoned, and then reinstate the patent application [see 19.11].

If an applicant chooses to submit a new amendment after allowance, the examiner will determine whether or not a new amendment after allowance fee is required. A new amendment after allowance fee will be required if the subject-matter of the new amendment after allowance is substantially different from that of the original submission.

19.09 Amendments after Commissioner's withdrawal of notice of allowance

September 2014

In the case where, after a notice of allowance has been sent to the applicant but prior to the patent being issued, the Commissioner has reasonable grounds to believe that the application does not comply with the *Patent Act* and *Patent Rules*, the Commissioner will notify the applicant accordingly and will return the application to the examiner for further examination. If the final fee has been paid, it will be refunded as per subsection 30(7) of the *Patent Rules*. Prosecution of the application will resume and the application may be amended by the applicant.

19.10 Amendments with or after payment of the final fee

June 2016

Generally, applications may not be amended by the applicant after the final fee has been paid (subsection 33(1) of the *Patent Rules*). On receipt of such an amendment submission, the Patent Office will notify the applicant that the application is scheduled to issue and cannot be amended, with the exception of clerical errors as provided by section 8 of the *Patent Act* [see 23.04 of this manual]. If a request to correct a clerical error is received after payment of the final fee, but before issue, the correction will be made after the patent issues.

19.10.01 Amendments after allowance submitted with the final fee

As noted above [see 19.10], an application shall not be amended after payment of the final fee. **Applicants are strongly advised not to submit the final fee at the same time as an amendment after allowance (AAA)**. Should the Office inadvertently apply the final fee before processing the AAA, the AAA will not be taken into account and the application will proceed to grant on the basis of the application as it stood at the time of allowance. Though paragraph 4(10)(*b*) of the *Patent Rules* provides that a final fee may be refunded if a refund request is received before the start of technical preparations for issue, the Office now begins technical preparations for issue **a short time after receipt of the final fee**, making it highly unlikely that the Office will be able to refund the final fee.

The following procedures will be followed by the Office when an AAA is submitted at the same time as the final fee:

1. Where the cover letter does **not** instruct the Office that the final fee is only to be applied in the event that the amendment after allowance is acceptable:
    - The final fee will be applied once the amendment after allowance has been evaluated by an examiner.
    - If the amendment after allowance is acceptable, it will be entered and the final fee will be applied. The application will proceed to grant and will include the amendment after allowance.
    - If the amendment after allowance is not acceptable, the amendment will not be entered; the final fee will be applied and the application will proceed to grant on the basis of the application as it stood at the time of allowance.
    - In both cases the Office will send a courtesy letter informing the applicant whether or not the amendment after allowance was accepted. Please note that in this instance the final fee will have been applied before the courtesy letter is sent.

2. Where the cover letter does instruct the Office that the final fee is only to be applied in the event that the amendment after allowance is acceptable:
    - If the amendment after allowance is acceptable, the amendment will be entered and the final fee will be applied. The application will proceed to grant and will include the amendment after allowance.
    - If the amendment after allowance is not acceptable, the amendment will not be entered. The final fee will not be applied and the application will go abandoned at the expiry of the time to pay the final fee, unless a subsequent acceptable amendment after allowance is received before the expiry of the time to pay the final fee.
    - In both cases the Office will send a courtesy letter informing the applicant whether or not the amendment after allowance was accepted.

19.11 Amendments after failure to pay the final fee

September 2014

If an applicant fails to pay the final fee within the six-month period after the date of the notice of allowance, the application will be deemed abandoned (paragraph 73(1)(*f*) of the *Patent Act*).

Subsequent to abandonment, the applicant has 12 months within which the application may be reinstated under subsection 73(3) of the *Patent Act*. In order to reinstate the application, the applicant must file a request for reinstatement along with the payment of the reinstatement fee and payment of the final fee. Should the applicant wish to amend the application at this stage, the amendment request must be made together with the request for reinstatement. The amended application will be considered with respect to compliance with the *Patent Act* and *Patent Rules* upon receipt, and the application will be subject to examination, pursuant to subsection 73(4) of the *Patent Act*. If the application is found to be allowable, it will advance directly to issuance since the final fee has already been paid. If the application does not meet the requirements of the *Patent Act* and *Patent Rules*, prosecution of the application will resume.

Endnotes for Chapter 19

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[i] *Re: Application No. 139,256* (Patent No. 1,029,723) [1977] 51 C.P.R. (2d) 95 at 103; *Re Application No. 315,073* [(1981) C.D. 904]; *Re Application No. 2,313,707* [(2013) C.D. 1353]

Chapter 20
Withdrawal, abandonment, reinstatement, lapse and time limits

20.01 Withdrawal of an application June 2015

An application may be withdrawn at any time. A request for withdrawal must be in writing from the authorized correspondent on behalf of the applicant (subsection 6(1) of the *Patent Rules*). Any fee which has been paid prior to the date of withdrawal is not refundable except under subsections 4(3) and (4) of the *Patent Rules*.

Withdrawal of an application prior to the application being opened to public inspection may prevent publication of the application [see section 2.01.02 of this manual].

An application which is withdrawn after being opened to public inspection will remain publicly accessible.

20.02 Abandonment June 2015

An application shall be deemed abandoned under subsection 73(1) or 73(2) of the *Patent Act* if the applicant does not:

- reply in good faith to any requisition of an examiner within the time limit specified (see Chapter 13 and section 19.06 of this manual);
- complete the application and pay the completion fee within the time limit specified (see Chapter 5 of this manual);
- pay the prescribed maintenance fees within the time limit specified (see chapter 24 of this manual);
- make a request for examination or pay the prescribed fee within the time limit specified (see Chapter 13 and section 14.10 of this manual);
- make a request for examination or pay the prescribed fee, when required to do so by the Commissioner, within the time limit specified (see chapter 13 of this manual);
- pay the final fee within the time limit specified (see chapter 13 of this manual); or
- comply with any requisition of the Commissioner within the time limit specified (sections 97 and 151 of the *Patent Rules*).

Each failure of the applicant to act as detailed above will result in a separate cause of abandonment. Therefore an application can be subject to multiple concurrent or overlapping abandonments.

The provisions for abandonment are a matter of law and do not allow for the exercise of discretion by the Commissioner. It is the duty of the applicant to meet the obligations necessary to avoid abandonment[1].

20.03 Reinstatement June 2015

Where an application becomes abandoned under subsection 73(1) or 73(2) of the *Patent Act*, the applicant may reinstate the application according to subsection 73(3) of the *Patent Act* and section 98 or 152 of the *Patent Rules* within twelve months of the date the application was deemed abandoned by:

i) making a request for reinstatement,
ii) taking the action that should have been taken in order to avoid the abandonment, and
iii) paying the fee set out in item 7 of Schedule II of the *Patent Rules*.

The time limit for reinstatement may be extended under subsection 26(1) of the *Patent Rules* provided that the request for the extension of time is made before the period for reinstatement expires and the fee set out in item 22 of Schedule II of the *Patent Rules* is paid before the period for reinstatement expires. If the applicant takes no action prior to the expiry of the twelve-month reinstatement period, the application cannot be reinstated. No retroactive extensions are available.

The provisions for reinstatement are a matter of law and do not allow for the exercise of discretion by the Commissioner. It is the duty of the applicant to meet the requirements necessary to reinstate an application[2].

Where an application is abandoned for more than one failure to act, the applicant must take the required actions for each failure to act within twelve months of each respective date of abandonment (sections 98 and 152 of the *Patent Rules*).

Example:

An application has become abandoned on two grounds:

- the applicant failed to respond to an examiner's requisition within the six month time limit (the response was due on June 2, 2013); and
- the applicant failed to pay a maintenance fee that was due on July 10, 2013.

In order to reinstate the application, the applicant must do the following:

- request reinstatement;
- respond to the examiner's requisition and submit a reinstatement fee as outlined in item 22 of Schedule II of the *Patent Rules* by June 2, 2014; and
- submit the maintenance fee and a separate reinstatement fee as outlined in item 22 of Schedule II of the *Patent Rules* by July 10, 2014.

If the applicant attempts to reinstate but only responds to the examiner's requisition and pays only one reinstatement fee, the application will remain abandoned for failure to pay the maintenance fee; the time limit for reinstatement will be the end of the twelve-month period from the date the maintenance fee was due (i.e. July 10, 2014).

20.04 Lapsed patent June 2015

A lapsed patent is one which no longer confers any patent rights to the patentee because the appropriate maintenance fees have not been paid within the applicable time limit (see Chapter 24 of this manual).

A patent is deemed to have lapsed at the expiration of the time specified in items 31 and 32 of Schedule II of the *Patent Rules* (subsection 46(2) of the *Patent Act*). **A lapsed patent cannot be revived.**

Notification of lapsed patents will be published in the Canadian Patent Office Record.

20.05 Time limits June 2015

Time limits corresponding to various topics are covered in the chapter that deals with a topic in question. For example, for a discussion of time limits associated with priority requests see Chapter 7 of this manual.

20.05.01 Time limits expressed in "months"

Applications become abandoned or reinstated if certain actions are taken or not taken within definite time limits, usually expressed in a certain number of months. When a requisition is made for an action to be taken within a fixed number of months and the final month has no day of the month corresponding to the day of the month of the requisition, then the last day of the final month is the date the action must be completed. Thus an examiner's requisition with a time limit of six months which is issued on August 29, 30, or 31 must be replied to by February 28 (or February 29 in leap years). Similarly a requisition issued on March 31 setting three months for reply requires a response by June 30.

20.05.02 Time limits expiring on a dies non

When the last day upon which an applicant or a patentee may act on an application or patent falls on a day when the Patent Office is closed for business, the action may be taken on the next day the Patent Office is open (subsection 78(1) of the *Patent Act*). If the failure to act sets up new time limits (such as a reinstatement period), the new period starts to run from the extended date, rather than from the original date when the action was due.

Example:

A notice of allowance is issued on June 25, 2014 and has a time limit for payment of the final fee of six months. The final fee would then be due on December 25, 2014. However, as the Patent Office is closed December 25 and 26 for the statutory holidays and December 27 and 28 fall on a weekend, the final fee will be due on December 29, 2014. If the final fee is not paid on or before December 29, 2014, the application will be deemed to be abandoned on December 29, 2014. If final fee is not be paid by December 29, 2014 and the application becomes abandoned, it could be reinstated by requesting reinstatement and paying the appropriate fees on or before December 29, 2015.

20.05.03 Extensions of time

Under subsection 26(1) and section 27 of the *Patent Rules*, the Commissioner may extend the time limits associated with:

- a requisition concerning the appointment of a patent agent;
- a requisition by the Commissioner;
- an appeal to the Federal Court of a decision of the Commissioner under section 19, 19.1, subsection 20(3), 20(15), or 31(6) of the *Patent Act*; or,
- reinstatement.

Under subsection 35(2) of the *Patent Act*, where the Commissioner by notice requires an applicant to make a request for examination pursuant to subsection (1) or to pay the prescribed fee within the time specified in the notice, the Commissioner may extend the time limit to comply with the notice but the time cannot be extended beyond the later of five years from the filing date or, if applicable, six months after filing a divisional application (subsection 96 of the *Patent Rules*).

Under paragraph 73(1)(a) of the *Patent Act* and subsection 26(2) of the *Patent Rules,* where the Commissioner has set a shorter period for replying in good faith to any requisition made by an examiner, the Commission can extend the time limit to respond to the examiner's requisition but the time cannot be extended beyond six months from the date of the requisition.

In the cases listed above, the applicant must apply for the extension of time before the expiry of the original time limit and pay the fee set out in item 22 of Schedule II of the *Patent Rules*. While no affidavit is required when requesting an extension of time, the applicant must explain why the required actions cannot be completed within the time period originally set. Where the Commissioner is satisfied that the circumstances justify the extension, an extension will be granted.

The applicant will be notified by letter of the Commissioner's decision regarding any request for an extension of time associated with the time limits listed above.

The Commissioner cannot extend the time limits associated with:

- requesting priority (subsections 88(5) and 142(2) of the *Patent Rules*);
- filing a divisional application (subsections 36(2), 36(2.1) and 36(3) of the *Patent Act*);
- completing an application (subsections 94(4) and 148(2) of the *Patent Rules*);
- deposits of biological materials (subsections 104(5) and 160(5) of the *Patent Rules*);
- requests for examination (subsections 96(3) and 150(3) of the *Patent Rules*);
- appeals to a Federal Court concerning a refusal of an application (section 41 of the *Patent Act*);
- paying the final fee (subsection 30(11) of the *Patent Rules*);
- applying for a reissue patent (subsection 47(1) of the *Patent Act*);
- an appeal of a re-examination board decision (subsection 48.5(2) of the *Patent Act*); and,
- maintenance fees (sections 102 and 157 of the *Patent Rules*).

Endnotes

[1] *DBC Marine Safety Systems Ltd v Canadian Patents (Commissioner)*, 2007 FC 1142 at para 31 aff'd 2008 FCA 256.

[2] *DBC Marine* (supra at 1) at paras 33-34.

Chapter 21
Final Actions and Post-Rejection Practice

21.01 Scope of this chapter – December 2013

This chapter addresses examination practice surrounding the rejection of an application by an examiner, the writing of a *Final Action* to inform the applicant of the rejection, and the review of a rejected application by the Patent Appeal Board and the Commissioner of Patents.

Where an examiner, after having previously identified one or more defects in an application and having requisitioned the applicant to amend the application in order to comply with the *Patent Act* and *Patent Rules* or to provide arguments as to why it does comply, has considered the applicant's response and has reasonable grounds to believe that the application still does not comply with the *Patent Act* or *Patent Rules* and that the applicant will not amend the application to comply, the application may be rejected.

A *Final Action* is the examiner's report that notifies the applicant that their application has been rejected and that sets forth the examiner's reasons for the rejection. In essence, rejecting an application and writing a *Final Action* is a mechanism that resolves impasses between an examiner and an applicant.

This chapter provides guidance on determining when a *Final Action* is warranted, the content of the *Final Action* itself, and the various post-rejection practices that lead to disposal of the application by allowance or refusal. A significant portion of the chapter details the practices of the Patent Appeal Board during the review of a rejected application by the Commissioner of Patents.

21.02 Overview – December 2013

As is discussed in Chapter 13 of this manual, the examination of a patent application involves its consideration by a patent examiner.

Where, after examining the application, the examiner has reasonable grounds to believe that it complies with the *Patent Act* and *Patent Rules*, the examiner will approve the application for allowance [see section 13.11 of this manual].

Where, instead, the examiner considers that the application does not comply with the *Patent Act* or *Patent Rules*, the examiner will, in accordance with subsection 30(2) of the *Patent Rules*, inform the applicant of the application's defects and requisition the applicant to amend the application to comply or to provide arguments as to why it does [see section 13.07 of this manual].

Examination typically proceeds through an exchange of examiner's reports and responses from the applicant. The aim of this process is to reach a conclusion as to the allowability of the application.

In some cases, the examiner and applicant will reach an impasse as to whether an identified defect truly is a defect. Where this occurs, the examiner will reject the application and notify the applicant in a *Final Action*.

Subsection 30(3) of the *Patent Rules* provides that:

> *Where an applicant has replied in good faith to a requisition referred to in subsection (2) within the time provided but the examiner has reasonable grounds to believe that the application still does not comply with the Act or these Rules in respect of one or more of the defects referred to in the requisition and that the applicant will not amend the application to comply with the Act and these Rules, the examiner may reject the application.*

As will be seen later in the chapter, an applicant's ability to amend the application after it has been rejected may be limited. Consequently, although an application can, in principle, be rejected as soon as an impasse occurs with respect to a single defect, in practice a rejection will usually not occur if the examiner considers that continued correspondence with the applicant is serving to resolve other substantive defects.

Broadly speaking, it is desirable for a *Final Action* to be written when all defects have been resolved other than those on which an impasse exists. In practice, where this would unduly prolong prosecution, a *Final Action* can be written even though an impasse has not been reached with respect to some defects. Furthermore, where an impasse has been reached on all the substantive issues previously identified as defects, but new defects (substantive or otherwise) were introduced by the applicant, these new defects can be identified in a *Final Action*.

The decision as to when it is appropriate to reject an application must be made considering the overall context of examination, including the length of prior prosecution, the nature of the outstanding defects remaining, the extent to which these had been discussed by the examiner and the applicant, and whether the examiner considers it likely that further prosecution would advance the application to allowance.

Subsequent to a rejection, the examiner will review any responses to the *Final Action* that were made by the applicant before the expiry of the time to respond. Where the examiner does not withdraw the rejection, the Patent Appeal Board and the

Commissioner of Patents will review the rejected application, possibly in light of further submissions by the applicant. Following the review, the Commissioner may allow or refuse the application, or indicate a period of time during which the application may be amended in a manner specified by the Commissioner, such that it would be allowable if so amended but will otherwise be refused.

When an application has been refused by the Commissioner, the applicant may appeal the Commissioner's decision to the Federal Court.

21.03 Examination before a rejection – December 2013

At each stage of examination, an examiner will endeavour to identify all the defects in the application and inform the applicant of these in a report in accordance with subsection 30(2) of the *Patent Rules* [see sections 13.06 and 13.07 of this manual].

Early in prosecution, it is possible that certain defects are interrelated, complicating their identification and resolution. Ambiguity in a claim, for example, could make it difficult to conclusively determine whether the claimed matter is novel or unobvious. As prosecution advances, the applicant's amendments and arguments in response to a requisition may serve to change the examiner's understanding of the invention. It is, thus, understandable that different or additional defects may be identified in subsequent reports.

It is also possible that an examiner may miss a defect during the analysis of the application; nevertheless it is required that the examiner identify these defects once aware of them.

As prosecution advances, it may become apparent that the examiner and applicant do not agree as to whether certain defects are present. Typically, where an applicant responds to a requisition by providing arguments as to why the application does comply but the examiner still considers that the application is defective, a further report identifying this same defect will provide a greater level of detail regarding the examiner's analysis. As appropriate, the applicant's arguments will be addressed in the examiner's subsequent report.

Where it appears that prosecution is approaching an impasse, an examiner will usually advise the applicant of this fact by indicating in the report being written that a further report on substantially the same points may be made final. Although it is not a requirement of the *Patent Act* or *Patent Rules* that such a warning be provided, it should be done whenever doing so would be reasonable in the circumstances.[1]

The last report written before a *Final Action* (informally referred to as a "pre-final" action) should provide completely elaborated arguments supporting the examiner's conclusion that the application is defective. Recognising that the applicant's opportunities to amend the application subsequent to the expiry of the time to respond to a *Final Action* may be limited under subsection 30(6) of the *Patent Rules*, it is very important to ensure that all defects have been identified in a "pre-final" action. The limitations on amending the application post-rejection provide the reason for advising the applicant that the examiner is considering making the next report a *Final Action*: knowing their application faces imminent rejection, the applicant may consequently wish to take special care in responding to the pre-final action.

21.04 Rejecting an application – December 2013

An examiner may reject an application where the requirements of subsection 30(3) of the *Patent Rules* are met, namely

1) an examiner has previously identified a defect in an application, and requisitioned the applicant to amend the application in order to comply with the Act and Rules or to provide arguments as to why it does comply;
2) the applicant has responded to the requisition, but the examiner considers that the application still does not comply with the Act or Rules in respect of one or more of the defects referred to in the requisition; and
3) the examiner believes that the applicant will not amend the application to comply with the Act and Rules.

Having rejected the application, the examiner then notifies the applicant of the reasons for having rejected the application under the provisions of subsection 30(4) of the *Patent Rules*, namely

> *Where an examiner rejects an application, the notice shall bear the notation "Final Action" or "Décision finale", shall indicate the outstanding defects and shall requisition the applicant to amend the application in order to comply with the Act and these Rules or to provide arguments as to why the application does comply, within the six-month period after the requisition is made or, except in respect of Part V, within any shorter period established by the Commissioner in accordance with paragraph 73(1)(a) of the Act.*

Considering the guidance in section 21.03, it can be understood that the analysis of the defects identified in a *Final Action* is to be comprehensive in nature. Identifying a defect for the first time in a *Final Action*, while occasionally necessary, is generally not desirable. In particular, if a major defect (anticipation, obviousness, lack of utility, non-statutory subject matter, insufficiency, etc.) was overlooked in prior prosecution, a further regular requisition identifying the defect is most likely necessary in order to allow the applicant an opportunity to have their response be evaluated prior to any rejection.

If a new, significant defect was introduced with amendments made in response to the previous report, the examiner will have to exercise judgement as to whether or not a *Final Action* is appropriate.[2]

While reasonable efforts must be made to avoid identifying a defect for the first time in a *Final Action*, it is also necessary to consider the effect of unduly prolonging prosecution. Where a new defect is introduced by the applicant late in prosecution, it may not be appropriate to delay rejection simply to deal with it. Furthermore, where a newly identified defect is readily understandable and easily fixed (e.g. a missing antecedent, incorrect claim numbering, etc.), it may not be necessary to delay rejection.

What should not be done, however, is to ignore an identified defect in order to simplify the *Final Action*. The examiner must decide whether a newly identified defect requires a further report under subsection 30(2) of the *Patent Rules* or if it can be included in a *Final Action*.

21.04.01 The *Final Action* Report – December 2013

A *Final Action* is a particular type of examiner's report, and will usually not follow the regular style and form of a report written under subsection 30(2) of the *Patent Rules*.

The opening paragraph of a *Final Action* will identify that it contains a requisition under subsection 30(4) of the *Patent Rules*, and will feature the words FINAL ACTION prominently. The report will also include an indication that the application is being rejected pursuant to subsection 30(3) of the *Patent Rules*.

The preamble of the report should identify, in broad terms, the defects that have led to the rejection and which claims are considered defective and which are allowable.

The entire report should be drafted bearing in mind the point of dispute. Where the examiner and the applicant agree on certain facts or conclusions pertaining to the disputed defect, this should be noted (with reference to any relevant correspondence) but it is not necessary to comprehensively revisit these aspects.[3]

The goal of the *Final Action* is to make the point of disagreement clear, to set out the applicant's position as understood by the examiner, and the examiner's reasoning for considering the application to still not comply with the Act or Rules. The *Final Action* should be drafted so that interested persons reading it (including the applicant, Patent Appeal Board, the Commissioner or the Court) can readily understand the point of the dispute and the examiner's reasons for concluding that the application does not comply with the Act or Rules despite any arguments to the contrary from the applicant.

Although the actual layout and presentation of a *Final Action* can be tailored to fit the facts of the case under consideration, the following information should be provided where relevant.

1) A summary of the application, setting forth the invention as claimed with an emphasis on the relevant claims. The summary should clearly identify any aspects of the claims that are central to the impasse.

2) An identification of any allowable claims.

3) An identification of any relevant prior art and a discussion of the pertinent teachings of those disclosures.

4) A summary of the relevant prior prosecution, setting forth in broad terms how the discussion of the alleged defect has proceeded. This section may also provide a summary of the applicant's reasons for believing the application is not defective.

5) A discussion of the legal, jurisprudential and administrative considerations relevant to the impasse, particularly where these are central to the dispute.

6) The grounds for rejection, which should provide a comprehensive analysis of the defects that led to the rejection, including a rebuttal where appropriate of the applicant's arguments.

7) A summation, wherein the grounds for rejection are very briefly recapitulated.

It may be beneficial to divide the report into sections, using clear headings to identify what is being discussed in each section.

To the extent practical, the *Final Action* should be written so that it can be understood independently of other reports or responses. More particularly, pertinent arguments should not be incorporated by reference to other documents but should, minimally, be summarised in the *Final Action* itself.

21.05 Responses to a *Final Action* – December 2013

An applicant may respond to a *Final Action* by submitting amendments to make the application compliant with the *Patent Act* and *Patent Rules* or by submitting arguments as to why the application does comply.

Upon receipt of a response to the *Final Action* before the expiry of the time to respond, the examiner will review the application.

21.05.01 Responses that overcome the rejection

If, after considering any amendments and arguments submitted by the applicant, the examiner considers that the application complies with the Act and Rules, it will be allowed pursuant to subsection 30(5) of the *Patent Rules*, which provides that

> *If before the expiry of the period under subsection (4), the applicant amends the application or provides arguments and the examiner has reasonable grounds to believe that the application complies with the Act and these Rules,*
>
> > *(a) the examiner shall notify the applicant that the rejection is withdrawn; and*
> >
> > *(b) the Commissioner shall notify the applicant that the application has been found allowable and requisition the payment of the applicable final fee set out in paragraph 6(a) or (b) of Schedule II within the six-month period after the date of the notice of allowance.*

The notification under paragraph 30(5)(*a*) of the *Patent Rules* takes the form of an Office letter sent to the applicant by the examiner. It is a separate piece of correspondence from the notice of allowance.

21.05.02 Responses that do not overcome the rejection

If, after considering any amendments and arguments submitted by the applicant, the examiner considers that the application still does not comply with the Act or Rules, the examiner's next steps depend on whether the time to respond to the requisition has expired or not.

If the time to respond has not expired, the examiner may contact the applicant to inform them of the examiner's conclusions and to determine whether the applicant wishes to submit further amendments and/or arguments prior to the expiry of the time to respond to the requisition. This would be particularly appropriate in instances where the applicant has partially addressed the grounds for rejection and where it appears a further response could make the application allowable.

If the time to respond to the requisition has expired, the provisions of subsection 30(6) of the *Patent Rules* apply. Thus,

> *If the applicant amends the application or provides arguments within the time referred to in subsection (4) but, after the expiration of that time, the examiner does not have reasonable grounds to believe that the application complies with the Act and these Rules,*

> *(a) the Commissioner shall notify the applicant that the rejection has not been withdrawn;*
>
> *(b) any amendments made within the time referred to in subsection (4) shall be considered not to have been made; and*
>
> *(c) the rejected application shall be reviewed by the Commissioner.*

By virtue of paragraph 30(6)(*b*) of the *Patent Rules*, any amendments made after the *Final Action* was sent are considered not to have been made unless the examiner determines that they place the application in condition for allowance. If, after the time for responding to the *Final Action* has expired, an examiner concludes that the application is still not allowable, the examiner will prepare the case for review by the Commissioner.

21.06 The Summary of Reasons – December 2013

A *Summary of Reasons* is a document written by an examiner in preparation for the Commissioner's review of a rejected application pursuant to paragraph 30(6)(*c*) of the *Patent Rules*. It is written only when the time to respond to the *Final Action* requisition has expired and the applicant's response has not overcome the reasons for rejection [see 21.05.02].

In the *Summary of Reasons*, the examiner briefly sets out why they still do not have reasonable grounds to believe that the application complies with the *Patent Act* and *Patent Rules*. Since the rejection is being maintained, any amendments proposed by the applicant subsequent to the rejection are considered not to have been made. Consequently, the examiner's reasons for considering the application not to comply with the Act and Rules will primarily be those set out in the *Final Action* itself. Reasons given in the *Final Action* should not be comprehensively repeated in the *Summary of Reasons*, which (as its name implies) is intended to be a brief document.

The *Summary of Reasons* should identify and address any new considerations arising from the applicant's post-rejection correspondence received up to the expiry of the time to respond to the requisition, such as new arguments in support of patentability, relevant jurisprudence or changes to Office practice.

If the applicant has proposed amendments, the examiner should provide a concise analysis of the effect of these amendments. The *Summary of Reasons* will provide information such as whether proposed amendments would have overcome, or addressed in part, certain of the examiner's grounds for considering the application defective or would have changed the examiner's reasons for considering the claims defective. It would be particularly noted if the proposed amendments would have rendered certain claims allowable. Similarly, any defects present in the proposed amendments would be identified.

It should also be indicated if certain of the applicant's arguments were compelling, even if the arguments themselves were insufficient to give the examiner reasonable grounds to consider the application to comply with the Act and Rules. This might be the case, for example, where an applicant explains how the invention may be distinguished from cited prior art, but the arguments are based on features not defined in the claims.

In view of the above, it can be understood that the *Summary of Reasons* is intended to assist in the review of the application by providing a concise, high-level overview of important considerations arising from any post-rejection correspondence with the applicant as well as any information relevant to the review which was not available at the time the application was rejected.

21.07 Review of a rejected application – September 2017

A review of a rejected application is, as previously noted, required by subsection 30(6) of the *Patent Rules* whenever the applicant's response to a *Final Action* does not place the application in condition for allowance.

While the review is primarily focused on resolving the impasse that led to a rejection, the review is also comprehensive, meaning that any apparent defects in the application, even beyond those indicated in the *Final Action* and/or the *Summary of Reasons*, will be identified at this stage.[4] This point is highlighted in paragraph 30(6)(*c*) of the *Patent Rules* which states that the "rejected application" is reviewed.

It can be broadly stated that the intention of the review process is to achieve efficiency, finality, and compliance of the application with the *Patent Act* and *Patent Rules* while adhering to the principles of natural justice and procedural fairness.

The review of an application can be terminated by withdrawing the application, and will typically not proceed during periods where the application is deemed abandoned by operation of law. The review is also terminated where an application remains abandoned outside the reinstatement period.

21.07.01 Referral to the Patent Appeal Board

The Commissioner is assisted in performing the review of a rejected application by the Patent Appeal Board (PAB).[5] The PAB is an advisory body consisting of a Chair and several members, each of whom is a senior official of the Patent Office with previous experience as a patent examiner. The review of a specific application is typically performed on behalf of the Commissioner by a panel of three members of the PAB. In order that the review of the application be impartial, these members must not have participated in the prosecution of the application or have previously given advice in respect thereto.

The review occurs only after the time limit for responding to the *Final Action* has expired and the *Summary of Reasons* has been prepared and forwarded to the PAB. At this point, control over the application is transferred to the PAB.

It is to be noted that the review process is an *ex parte* process, meaning that there is only one party to the proceedings, namely the patent applicant. The process is a continuation of the administrative procedures of the office with regard to patent applications under the *Patent Act*, but is performed at arm's length to the examination divisions.

21.07.02 Communication with the applicant

During the review process, an applicant can expect to be contacted by the Board several times. These communications may cover both administrative and substantive matters relating to the review.

Administrative matters include informing the applicant that the application has been transferred to the PAB and details relating to giving the applicant an opportunity to be heard.

Substantive matters include keeping the applicant informed of any matters affecting the review, including providing the applicant with a copy of the *Summary of Reasons*.

When a rejected application is transferred to the PAB, the applicant is informed in an initial letter from the Board. This initial letter will, minimally, notify the applicant, as required by paragraph 30(6)(*a*) of the *Patent Rules*, that the examiner's rejection has not been withdrawn [see 21.05.02] and that the case has been transferred to the PAB. A copy of the *Summary of Reasons* [see 21.06] will accompany the letter.

Where the applicant responded to the *Final Action* by submitting amendments, the initial letter will also confirm, per paragraph 30(6)(*b*) of the *Patent Rules*, that because the rejection was not withdrawn, any amendments received in response to the *Final Action* within the time referred to in subsection 30(4) are considered not to have been made.

Additional information relating to the review, including the offer of an opportunity to be heard, may be included in the initial letter or dealt with separately.

Communications from the PAB generally include a time period to respond. It is important to note, however, that a letter from the PAB is not a requisition. If it is not responded to within the time period stated, the application will not be deemed abandoned. Consequently, failure to respond to a PAB communication will not suspend the review process.

21.07.03 Issues arising during the review process

During the review, the panel may come to believe that defects beyond those identified in the *Final Action* are present in the application. The identification of such defects may result, for example, from the panel interpreting the application differently from the examiner, or be in view of different interpretations of jurisprudence or office practices, or be in view of new art submitted through a late-filed protest, art cited in recent foreign prosecution or a change in the *Patent Act* or *Patent Rules*.

Where a new defect is identified during the review, the applicant is given notice of the issue and an opportunity to respond, which includes the possibility of proposing amendments to address the defect. Amendments proposed by the applicant, if they correct the defect, may be later required to be made by the Commissioner in a Commissioner's Decision under paragraph 31(*b*) of the *Patent Rules* [see 21.08.03]. The opportunity to respond is demanded both by the requirements of natural justice and by subsection 30(6.1) of the *Patent Rules*, which provides that:

> *If, during the review of a rejected application, the Commissioner has reasonable grounds to believe that the application does not comply with the Act or these Rules in respect of defects other than those indicated in the Final Action notice, the Commissioner shall inform the applicant of those defects and invite the applicant to submit arguments as to why the application does comply within the time specified by the Commissioner.*

Where a potential defect is identified during the review process, the panel may raise the matter directly with the applicant or may request that the examiner provide an analysis in relation thereto. In exceptional cases, the panel may also determine that a further search and analysis of the prior art is necessary in relation to the defect.

Where an analysis is requested of an examiner, the examiner's findings are presented in a *Supplemental Analysis*, a document similar in form to a *Summary of Reasons* but addressing only the issue identified by the panel.

Where a *Supplemental Analysis* is requested of an examiner, the applicant will be duly informed and will receive a copy of the analysis.

A response to a *Supplemental Analysis*, including proposed amendments, should only address the defect under consideration in the analysis.

21.07.03*a* Clarification of certain matters

It is desirable that the review proceed, as far as is reasonably practical, on the basis of a common understanding of the matters at issue. Therefore, in addition to the identification of new defects, it is also possible that the panel may wish to clarify certain other matters with the applicant during the review process.

Such clarifications are intended to ensure that the applicant and the panel have the same understanding of, for example, the examiner's grounds for rejection, the applicant's arguments, the applicable Office practice, or of certain relevant facts.

Where it appears to the panel that clarification is desirable, a memo will be sent to the applicant setting out the matters that, in the panel's view, may require clarification. Where the examiner's input is necessary, it may be provided in the form of a *Supplemental Analysis*.

The applicant will be given a period of time to respond, and may respond with written submissions or with oral arguments at the hearing.

21.07.04 Opportunity to be heard

Subsection 30(6.4) of the *Patent Rules* specifies that the applicant must be given an opportunity to be heard before any refusal. The applicant will therefore generally be invited to participate in a hearing. The PAB will make reasonable efforts to accommodate the applicant's schedule, but if the applicant is unable to participate in a timely hearing the review will proceed nonetheless.

The applicant is not required to attend a hearing, and may instead request that the review proceed on the basis of the written record.

Prior to any hearing, the panel will perform an initial review of the case both to ensure that the outstanding issues have been clearly identified and articulated and that there are no other issues requiring clarification, such as defects identified pursuant to subsection 30(6.1) of the *Patent Rules* [see 21.07.03].

The purpose of the hearing is to provide the applicant with a further opportunity to develop and explain the reasons for contending that the application is not defective (on the basis of the grounds raised either by the examiner or by the PAB during the review process) or that proposed amendments overcome the identified defects. Written arguments and/or additional evidence should be presented to the panel well ahead of the hearing, to ensure the panel has sufficient time to consider them. When any new legal or technical argument or fresh evidence relevant to the grounds raised by the examiner comes to the applicant's attention it should be presented as early as possible and not deferred until the review stage (i.e., the applicant's best case should be made during prosecution before the examiner and not only before the PAB).

The hearing may occur in person, via teleconference or via videoconference, at the option of the applicant, and may include the assigned panel, the applicant and applicant's patent agent and/or associate patent agent, as well as the examiner and the examiner's supervisor.

The hearing is primarily an opportunity for the applicant to present its position in order to advance prosecution, with input from the panel.

Typically a hearing begins with an oral presentation by the applicant. The panel may pose questions to the applicant during or after the applicant's presentation of arguments, depending both on the need to intervene and the applicant's preferences. The examiner and examiner's supervisor are normally present and may be called upon by the panel to answer questions in relation to the defect(s) and any technical matters. The applicant is given an opportunity to make any final comments before the conclusion of the hearing. No cross-questioning between the applicant and examiner is permitted.

Points of fact agreed to during the hearing, or concessions made by the applicant, will be taken into account in the recommendation to the Commissioner. Although it is expected that the applicant will be prepared to address any questions posed at the hearing, it may be acceptable, should an unexpected issue arise during discussion, for the applicant to make additional submissions to the panel within a reasonable period thereafter.

Since the panel must make a recommendation to the Commissioner, no decision regarding disposal of the application may be made at the hearing.

21.07.05 Decisions without a hearing

It is not necessary in every case to hold a hearing. As noted in 21.07.04, the applicant may decline the invitation for a hearing. Where this is done, the assigned panel will review the case and provide a recommendation to the Commissioner taking into account the written record before it, including any further written submissions the applicant has provided.

It is also possible that the panel, after its initial review of the case, may conclude that the application complies with the Act and Rules. Where the Commissioner agrees with this conclusion, there is no need to invite the applicant to attend a hearing. Subsection 30(6.4) of the *Patent Rules* does not require a hearing where the application will be allowed.

21.07.06 Recommendation to the Commissioner

At the conclusion of the panel's review, the panel will deliberate and formulate a recommendation to the Commissioner. The panel considers the facts and law related to the particular matter before them, including any arguments and evidence adduced by the applicant during the review.

The recommendation is provided as written reasons that generally include an explanation of the invention being considered, background information on the prosecution, an identification of the issues to be decided, relevant statutory authority, pertinent jurisprudence, a summary of the positions of the examiner and applicant, a detailed analysis of the issue(s) including factual findings, and a final recommendation of the panel.

The Commissioner of Patents is then briefed on the case and reviews the recommendation prior to rendering a final decision.

21.08 The Commissioner's Decision – June 2016

The Commissioner's Decision provides reasons for arriving at the decision and explains any findings with reference to the *Patent Act*, *Patent Rules* and pertinent jurisprudence. Typically, the Commissioner adopts the panel's reasons.

In addition to its importance to the applicant, a Commissioner's Decision can also provide insight and/or guidance to applicants and patent examiners as to the current understanding of the state of the law and Office practice. Commissioner's Decisions are carefully reviewed when practice guidance is provided to examiners.

A copy of the decision is sent to the applicant (by registered mail if the application is refused, as per section 40 of the *Patent Act*). These decisions become part of the prosecution file and are therefore open to public inspection, except for decisions made in respect of applications filed prior to October 1, 1989 which are only published with the permission of the applicant.

A database of published Commissioner's Decisions is maintained by the Office and may be accessed via the CIPO web site.

In the following sections, the possible outcomes of Commissioner's Decisions are set out, along with the effect of each.

21.08.01 Rejection not justified and application allowable

Subsection 30(6.2) of the *Patent Rules* provides that

> *If, after review of a rejected application, the Commissioner determines that the rejection is not justified on the basis of the defects indicated in the Final Action notice and has reasonable grounds to believe that the application complies with the Act and these Rules, the Commissioner shall notify the applicant that the rejection is withdrawn and that the application has been found allowable and shall requisition the payment of the applicable final fee set out in paragraph 6(a) or (b) of Schedule II within the six-month period after the date of the notice of allowance.*

In such a case the applicant will be notified in the Commissioner's Decision that the rejection is withdrawn and that the application will be allowed.

Once the application has been allowed, it is treated in the same manner as any other allowed application [see section 13.11 of this manual], with a Notice of Allowance being sent to the applicant requisitioning payment of the final fee.

21.08.02 Application refused

If upon review of the rejected application the Commissioner is of the view that the examiner's rejection is justified, or that the application does not comply with the Act or Rules on the basis of defects identified during the review process, and it is not evident that the application can be made compliant through a directed amendment per paragraph 31(*b*) of the *Patent Rules*, the Commissioner will refuse the application pursuant to section 40 of the *Patent Act*. The refusal will be indicated in the Commissioner's Decision which will also specify the applicable six month period in which to initiate an appeal to the Federal Court.

21.08.03 Amendments required by the Commissioner

As per subsection 30(6.3) of the *Patent Rules*

> *If, after review of a rejected application, the Commissioner determines that the application does not comply with the Act or these Rules, but that specific amendments are necessary, the Commissioner shall notify the applicant that the specific amendments have to be made within three months after the date of the notice. If the applicant complies with that notice, the Commissioner shall notify the applicant that the application has been found allowable and shall requisition the payment of the applicable final fee set out in paragraph 6(a) or (b) of Schedule II within the six-month period after the date of the notice of allowance.*

The applicant will be notified of the necessary amendments in the Commissioner's Decision pursuant to subsection 30(6.3) of the *Patent Rules* and will be invited to make the amendments pursuant to paragraph 31(*b*) of the *Patent Rules*. The amendments required in a Commissioner's Decision may be based on proposed amendments submitted during the review process, both as a result of the applicant's own initiative or as a result of defects identified during the review process. They may also be based on the Commissioner's findings alone as to how the application can be made compliant with the Act and Rules.

If in response to the requirement for amendment the applicant does not make the necessary amendments, or makes amendments beyond those required, the Commissioner will refuse the application in accordance with section 40 of the *Patent Act*.[6]

21.09 Appeals of Commissioner's Decisions – December 2013

Where the Commissioner refuses a patent application under section 40 of the *Patent Act*, section 41 of the Act states that

> *Every person who has failed to obtain a patent by reason of a refusal of the Commissioner to grant it may, at any time within six months after notice as provided for in section 40 has been mailed, appeal from the decision of the Commissioner to the Federal Court and that Court has exclusive jurisdiction to hear and determine the appeal.*

The decision of the Federal Court may be appealed to the Federal Court of Appeal and, with leave, to the Supreme Court of Canada.

21.10 Prosecution following a decision of the Court – December 2013

Following a decision of the Court, the Commissioner takes action in accordance with any resulting orders of the Court. Of note is that the Court has the authority to order the entering of amendments, per paragraph 31(*d*) of the *Patent Rules*

> *An application that has been rejected by an examiner in accordance with subsection 30(3) shall not be amended after the expiry of the time under subsection 30(4) for responding to the examiner's requisition except*
>
> *(a) by order of the Federal Court, the Federal Court of Appeal or the Supreme Court of Canada.*

Endnotes for chapter 21

1. A further report would not be written, for example, solely to advise the applicant that the next report may be made final, where the report otherwise simply reiterates the arguments presented in the previous report.

2. A further report may not be necessary, for example, where the examiner has previously identified a defect as a non-compliance with one section of the Act or Rules, but later realises that for the same or substantially the same reasons the defect in question results in non-compliance with a further section of the Act or Rules or that the defect should have been identified as non-compliance with a different section of the Act and Rules than that previously identified.

3. If the examiner had previously identified something as belonging to the common general knowledge, and the applicant had acknowledged this in correspondence, it would not be necessary to further substantiate that it is, in fact, common general knowledge. Similarly, if a claim with five elements was identified as being anticipated in view of a document D1, and the applicant agrees that D1 teaches four of the five claimed elements, it is not necessary to elaborate on those features in the reasons for the rejection; the point of disagreement is whether D1 discloses the fifth element.

4. Despite the fact that any apparent defects will be identified, a review begins with the presumption that the search and examination prior to the review stage is complete and comprehensive.

5. The PAB was created in a *"Notice to the Patent Profession" (re: creation of the PAB, general guidelines, and hearing procedure)* C.P.O.R., Aug. 4, 1970

6. Canada. (2013). Regulatory Impact Analysis Statement, Rules Amending the Patent Rules. In *Canada Gazette*, *Part II*, Vol. 147, No. 26, 18 December 2013.

Chapter 22
Patent Cooperation Treaty (PCT)

22.01 Patent Cooperation Treaty (PCT)

May 2014

The PCT is a multilateral treaty among States, concluded in 1970 and entered into force on January 24, 1978. Canada became bound by the PCT on January 2, 1990. As of July 26, 2004 Canada became an International Searching and Preliminary Examination Authority under the PCT.

Information regarding the Patent Cooperation Treaty (PCT) may be found at the following links.

PCT – The International System:

- General PCT information and resources
- Frequently Asked Questions about the PCT
- International Phase information (Where to apply, process, etc):
  PCT Applicant's Guide – International Phase
- National Phase information:
  PCT Applicant's Guide – National Phase
- For specific information relating to CIPO in its various roles in the PCT:
  Receiving Office (RO/CA) information
  International Searching Authority (ISA/CA) information
  International Preliminary Examination Authority (IPEA/CA) information
  National Phase Entry (DO/CA or EO/CA) information

For the PCT Treaty, Regulations and Administrative Instructions:

- Patent Cooperation Treaty (PCT):
- Regulations under the Patent Cooperation Treaty:
- Administrative Instructions under the Patent Cooperation Treaty

Information on the work of the Authorities and Offices can be found on WIPO's website.

Chapter 23
Disclaimer, re-examination, reissue and corrections of clerical errors

23.01 Disclaimer

December 2015

Disclaimer is a mechanism whereby a patentee may, at any time during the life of a patent, amend a patent to claim less than that which was claimed in the original patent. It is used where the patentee has, "by any mistake, accident or inadvertence, and without any wilful intent to defraud or mislead the public", made a specification "too broad" by claiming more than the inventor invented or subject-matter to which the patentee had no lawful right[1] (subsection 48(1) of the *Patent Act*). A disclaimer is not limited to a whole claim or claims. A part of a claim may be disclaimed,[2] provided that the disclaimer does not extend the scope of the claim or any claims depending on the claim.[3]

A filing of a disclaimer is a renunciation of subject-matter. A disclaimer is also a clear and unequivocal statement that the original patent claims are too broad and thus invalid.[4]

23.01.01 Filing a disclaimer

To file a disclaimer, Form 2 of Schedule I of the *Patent Rules* must be completed and filed with the Patent Office along with the appropriate fee set out in item 13 of Schedule II of the *Patent Rules* (subsection 48(2) of the *Patent Act* and section 44 of the *Patent Rules*). In completing Form 2, the patentee must follow the precise form of subsections 3(1) and 3(2), which specify the subject-matter disclaimed. The expression "...with the exception of the following:" in Form 2, subsection 3(2) indicates elements of the claim(s) remaining after the disclaimer, and cannot be used to reformulate or redefine the invention disclosed and claimed.[5]

23.01.02 The roles of the Patent Office and the Courts

The filing of a disclaimer does not involve any examination of the subject-matter of the claims by the Patent Office. The Patent Office only ensures that the disclaimer has been filed in the prescribed form and manner in accordance with subsection 48(2) of the *Patent Act* and section 44 of the *Patent Rules*. As long as the disclaimer is filed in the proper form and manner, and the prescribed fee has been paid, the Commissioner has no discretion to refuse to record it.[6]

The onus of showing that the disclaimer satisfies all the requirements of subsection 48(1) of the *Patent Act* rests with the patentee. Furthermore, there is no presumption of validity of the disclaimer.[7] The validity of the disclaimer depends on: the state of the mind of the patentee at the time of preparation of the specification;[8] whether the disclaimer is made in good faith and not for an improper purpose;[9] the length of time between discovering a problem with the patent and the filing of a disclaimer;[10] whether the disclaimer broadens the scope of the patent;[11] whether the disclaimer recasts an invention;[12] or, whether the disclaimer adds a new and different combination by the addition of elements to the claim.[13]

If the courts determine that the disclaimer is invalid, the disclaimed claims must return to how they were prior to the disclaimer. However, the disclaimed claims as they stood prior to the disclaimer are invalid[14] on the basis of being overbroad by admission of the patentee.[15]

23.01.03 Effect of a disclaimer

Disclaimers do not normally affect any court action pending at the time they are made (subsection 48(4) of the *Patent Act*).

Following a disclaimer, the remaining claims are deemed to be valid for the matter not disclaimed, i.e. in their disclaimed form (subsection 48(6) of the *Patent Act*). Thus a claim which is overly broad which has not been adjudged to be invalid may be saved from a finding of invalidity if a valid disclaimer is filed but only if filed in a timely way.[16]

The disclaimer is unconditional. The existing claims of the patent are the claims as amended by virtue of the disclaimer, and the only invention protected by the letters patent is that defined by such existing claims.[17]

23.02 Re-examination

December 2015

The purpose of re-examination is to provide a relatively summary and inexpensive alternative to an impeachment process by litigation or an opportunity for a patentee to have the Patent Office reconsider the claims of an issued patent.[18]

As noted by the Federal Court in *Prenbec v Timberblade*, re-examination proceedings are less comprehensive in nature than an impeachment action (para. 48). For example, unlike an action, a re-examination proceeding is limited to issues arising from the prior art supplied by the requesting party. Additionally, the re-examination board does not possess the means to test the credibility of contested issues of fact (para. 34) that are available to a Court, such as by hearing from live witnesses under cross-examination (para. 47).[19]

The re-examination process is set out in sections 48.1 to 48.5 of the *Patent Act*. Any person, including the patentee, may request re-examination of any claim or claims of a patent issued after October 1, 1989, at any time during the life of the patent, based on prior art. This applies to patent applications filed before October 1, 1989 which issued thereafter.

Upon receipt of an acceptable request for re-examination in accordance with subsections 48.1(1) and (2) of the *Patent Act*, re-examination proceeds in one or two stages, depending on the outcome of the first stage, both of which are *ex parte* in nature. If the requester is also the patentee they will participate in the second stage. In cases where the requester is not the patentee, any submissions from the requester beyond the filing of an acceptable request will not be acknowledged or taken into account during re-examination.

The first stage involves a preliminary decision by a re-examination board established by the Commissioner of Patents as to whether the request raises a substantial new question of patentability. The preliminary decision includes the re-examination board's reasons as to why a substantial new question of patentability is or is not raised by the request.

Where a substantial new question of patentability has been raised, the second stage involves the re-examination of the patent based on this question.

In the re-examination process, the board is not an adverse party as would be a competitor in an impeachment proceeding. The board's role is rather that of an adjudicator in an administrative context. The expertise of its members may be taken into account in any determinations which are made as part of the board's statutory duties.[20] In making factual determinations based on the record before it, such as who is the ordinary person skilled in the art and what was the relevant common general knowledge, there is no burden on a re-examination board to seek out and locate independent evidence to support these conclusions.[21] Such determinations are considered by a reviewing court based on a reasonableness standard and taking into account the board's expertise.[22]

The Patent Appeal Board is tasked with the administration of the re-examination process as part of its duties.

23.02.01 The request

December 2015

A written request for re-examination must be filed with the appropriate fee (see Schedule II, Part III, item 14 of the *Patent Rules*) and, if the requester is a small entity, a small entity declaration (subsection 3(6) of the *Patent Rules*).

The request must be based on prior art consisting of patents, applications for patents open to public inspection or printed publications (subsection 48.1(1) of the *Patent Act*). The request must set forth the pertinence of the prior art and the manner of applying the prior art to the claim or claims for which re-examination is requested (subsection 48.1(2) of the *Patent Act*). For example, the request may discuss why a particular claim is rendered anticipated under section 28.2 of the *Patent Act* in view of a prior art document.

The request, including copies of the prior art, must be provided in duplicate unless the requester is the patentee or the request is filed in electronic form (section 45 of the *Patent Rules*). In the case of duplicate copies one is for the re-examination board and the other for the patentee.

Any request for re-examination and the subsequent proceedings are made part of the electronic office file associated with the issued patent.

Upon receipt of a request for re-examination, a member of the Patent Appeal Board reviews the file on behalf of the Commissioner of Patents to ensure that the requirements of subsections 48.1(1) and 48.1(2) of the *Patent Act* and section 45 of the *Patent Rules* have been satisfied.

If the request satisfies these requirements and the requester is someone other than the patentee, then a package containing a copy of the request and a copy of the prior art is sent to the patentee. If the requester is the patentee, no such package is sent (subsection 48.1(3) of the *Patent Act*).

At the same time, the Commissioner of Patents establishes a re-examination board (subsection 48.2(1) of the *Patent Act*). The board must consist of not fewer than three persons, at least two of whom must be Patent Office employees. Generally, the re-examination board is composed of a Patent Appeal Board member serving as chairperson, and two patent examiners from the examination division to which the patent relates. The re-examination board members must not have participated nor advised in the examination of the application from which the patent issued.

Once the re-examination board is established, the patentee is informed of the composition of the board by the Commissioner who takes no further part in the re-examination process.[23]

Receipt of an acceptable request for re-examination and establishment of the re-examination board initiates the first stage of the re-examination process.

In the event that a request for re-examination does not satisfy the requirements of subsection 48.1(1) or 48.1(2) of the *Patent Act* or section 45 of the *Patent Rules*, the requester is so notified.

Examples of unacceptable requests are those which do not detail the pertinence of the prior art and the manner of applying said art to the claim or those which are based on material which would not qualify as "prior art" under section 48.1(1) of the *Patent Act*. At a minimum, an acceptable request should articulate the relationship between the features of the prior art and those of the claims for which re-examination has been requested.

A failure to include a duplicate copy of the request would also make the request unacceptable if the requester is not the patentee or the submission is not electronic. However, if a required duplicate copy has not been provided, the requester will be contacted and given the opportunity to provide one in order to complete the request. Likewise, if the requester is a small entity and has omitted a small entity declaration, the declaration may be submitted without resubmitting the entire request for re-examination.

Non-compliant requests for re-examination may be corrected and resubmitted without the requirement for a further fee. A request for re-examination is not considered to have been made until it is compliant with the requirements of the *Patent Act* and *Rules*. As such, no further action on the merits of the request is taken until an acceptable request is submitted.

If a request is compliant in respect to some claims but not for others, i.e. if the pertinence of the prior art is only discussed in relation to some of the claims requested for re-examination, then notification, establishment of the re-examination board and initiation of the first stage of re-examination will commence for the claims for which the request is compliant. The patentability of the claims for which the request is not compliant will not be further considered in the re-examination process.

The grant copy of a patent should never be submitted to the Patent Office when requesting re-examination.

23.02.02 First stage of re-examination: determination as to a substantial new question of patentability

December 2015

Within three months of establishment, the re-examination board must determine whether a substantial new question of patentability affecting any claim of the patent for which re-examination has been requested is raised by the request for re-examination (subsection 48.2(2) of the *Patent Act*). This is a threshold question which must be answered before any further re-examination of the patent can continue.

In order to raise a substantial new question of patentability the request must present an issue relating to the validity of one or more claims that was not previously considered during the prosecution of the application that resulted in the patent for which re-examination has been requested, and that was not considered during any other prior proceeding involving the patent. The issue must also not be so closely related to one previously considered such that it is not a substantial new question.

A substantial new question of patentability is most often raised by prior art that was not on record during the original prosecution. However, if prior art is so similar to that which was considered during examination that it would be applied in the same manner, there would not be any material effect on the record and substantial new question of patentability would not be established.

A substantial new question of patentability may be based on the same prior art considered by an examiner during the original examination so long as the requester is able to satisfy the board that the prior art was not applied in the same manner by the examiner (i.e. that a substantial "new" question is raised). For example, a piece of prior art may have been considered during examination as having been applicable as an anticipatory reference under section 28.2 of the *Patent Act*. As part of a request for re-examination the same piece of prior art might be used in combination with one or more other pieces of prior art to make a case for obviousness of a claim under section 28.3 of the *Patent Act*.

In the absence of evidence from the record as to how an examiner considered the prior art during prosecution (e.g., the application was allowed without an office action) the board will not presume that the prior art was considered in the same manner as outlined in the request.

If the re-examination board determines that the request for re-examination does not raise a substantial new question of patentability, the requester is so notified. This notice, which takes the form of a letter from the board, will include reasons as to why the board has reached such a conclusion. Such a decision by the board is final and not subject to appeal or review by any court (subsection 48.2(3) of the *Patent Act*).

In the event the board determines that the request for re-examination raises a substantial new question of patentability, the patentee is so notified in a letter which includes the board's reasons (subsection 48.2(4) of the *Patent Act*). These reasons are not limited to the arguments set out by the requester in the request for re-examination.

The patentee may reply within three months to the board's notice with submissions relating to the patentability of the claim(s) of the patent for which notice was given (subsection 48.2(5) of the *Patent Act*). At the same time, a patentee may submit proposed amendments to the patent to address the question of the patentability of the claim(s), so that the proposed amendments are before the board for the second stage of re-examination (subsection 48.3(2) of the *Patent Act*).

During all stages of the re-examination proceeding, if the requester is not the patentee, the board may send the requester copies of the correspondence from the board to the patentee as a courtesy.

23.02.03 Second stage of re-examination

December 2015

The re-examination of the patent based on the substantial new question of patentability begins upon a reply from the patentee or upon the expiration of three months from the notification from the board of a substantial new question of patentability (subsection 48.3(1) of the *Patent Act*).

In the event that there has been no reply from the patentee, as a courtesy the board will send a letter indicating that the re-examination of the patent has begun. The board will also advise the patentee that absent any further submissions a decision will be taken and a certificate of re-examination issued under subsection 48.4(1) of the *Patent Act*.

During the re-examination proceeding, there may be opportunity for multiple exchanges with the patentee in relation to the issues raised by the request. Letters from the board will set out the board's preliminary opinions on the patentability of the claims which are subject to re-examination and any proposed amendments made by the patentee. Final determinations on patentability are reserved until the issuance of a certificate of re-examination.

The patentee may propose any amendment to the patent (subsection 48.3(2) of the *Patent Act*), including amendments to the description and/or drawings. Any new claims proposed during re-examination must be numbered consecutively beginning with the number immediately following the number of the last claim of the issued patent (section 45.1 of the *Patent Rules*).

No amendment or new claim shall enlarge the scope of a claim of the patent (subsection 48.3(2) of the *Patent Act*). This provision is taken to mean that at a minimum any claim proposed during a re-examination proceeding must include all the features of the broadest independent claim of the patent. In other words, any proposed claim may not broaden the scope of protection in some respects even if the claim is narrowed in other respects.

As part of the exchanges between the board and the patentee during a re-examination proceeding the patentee may make submissions orally and/or in writing. Oral submissions may be conducted in person, via teleconference or via videoconference, at the option of the patentee.

Pursuant to subsection 48.3(3) of the *Patent Act*, the second stage of re-examination must be completed within twelve months.

23.02.04 Completion of re-examination

April 2018

The determinations of a re-examination board are functionally equivalent to a decision of the Commissioner of Patents under section 40 of the *Patent Act*. They are in essence a re-determination of the validity of the claims of the patent,[24] although within the particular circumstances set out in sections 48.1 to 48.5 of the *Patent Act*.

As such the re-examination board, like the Commissioner, must be satisfied that the patentee is not "by law" entitled to a claim of the patent in order for it to be cancelled. The same criteria would apply to a decision of the board not to incorporate a claim or other amendment into the patent with the additional requirement that such an amendment not enlarge the scope of a claim of the patent as per subsection 48.3(2) of the *Patent Act*.

Upon completion of the second stage of a re-examination proceeding, the re-examination board will issue a certificate of re-examination which is delivered to the patentee by registered mail (subsections 48.4(1) and 48.4(2) of the *Patent Act*). The certificate affects the original patent by:

(a) cancelling any claim of the patent determined to be unpatentable;
(b) confirming any claim of the patent determined to be patentable; or
(c) incorporating in the patent any proposed amended or new claim determined to be patentable.

If a certificate of re-examination indicates that an independent claim is cancelled from a patent, this does not mean that the text of the independent claim is no longer considered part of any dependent claim that refers to it. The cancellation of such a claim is a removal of the scope of protection afforded by the claim, not its text *per se*.
If any amendments have been proposed to the description and/or drawings which are determined to be permissible by the board under subsection 48.3(2) of the *Patent Act*, the incorporation of these amendments will be noted in the certificate of re-examination as well.

Accompanying the certificate of re-examination will be a decision from the board in the form of a letter to the patentee outlining the reasons for the board's determinations in the certificate.

Also accompanying the certificate of re-examination will be a registration certificate indicating that the certificate of re-examination issued by the board has been registered against the patent. In this way, the certificate is attached to the patent (subsection 48.4(2) of the *Patent Act*).

As a result of the re-examination proceeding a new cover page is generated for the patent indicating that the patent has been re-examined. The certificate of re-examination and any amendments to the patent are stored in association with the new cover page both in the Patent Office electronic file and on the Canadian Patent Database.

23.02.05 Effect of the re-examination certificate

December 2015

The effects of the certificate of re-examination are set out in subsection 48.4(3) of the *Patent Act,* namely :

> *[w]here a certificate…*
>
> *(a) cancels any claim but not all claims of the patent, the patent shall be deemed to have been issued, from the date of grant, in the corrected form;*
>
> *(b) cancels all claims of the patent, the patent shall be deemed never to have been issued; or*
>
> *(c) amends any claim of the patent or incorporates a new claim in the patent, the amended claim or new claim shall be effective, from the date of the certificate, for the unexpired term of the patent.*

Thus, the invalidity of a claim or claims as a result of re-examination is retroactive. However, the addition or amendment of claims has the effect of rights only being available for those claims for the remaining term of the patent.

The above effects do not apply until the appeal period has expired (see next section), and if an appeal is taken from the board's decision, the above effects only apply to the extent they are reflected in the final judgment of the courts (subsection 48.4(4) of the *Patent Act*).

Where the claims undergoing re-examination are confirmed, then said claims remain as issued for the unexpired term of the patent.

23.02.06 Appeals from re-examination

December 2015

A decision of the re-examination board that accompanies a certificate of re-examination can be appealed by the patentee to the Federal Court (subsection 48.5(1) of the *Patent Act*). The appeal must be taken within three months from the date that a copy of the certificate of re-examination is sent by registered mail to the patentee (subsection 48.5(2) of the *Patent Act*).

23.03 Reissue

December 2015

Reissue is a mechanism provided by section 47 of the *Patent Act* for correcting a "defective or inoperative" patent. Subsection 47(1) of the *Patent Act* sets out the conditions wherein a new reissued patent may be granted to a patentee.

The purpose of the reissue provision has been described as being to provide that kind of relief which courts of equity have always given in case of clear accident and mistake in the drawing up of written instruments.[25]

It is important to note that in accordance with the provision that the Commissioner of Patents "may" cause a new patent to be granted, the granting of a reissue is a discretionary measure. However, such discretion can only be exercised once the conditions of subsection 47(1) have been met. Any application for reissue which does not fall within the statute must be refused.[26] Any such exercise of discretion must also be compatible with the purpose of the reissue provision, as noted above.[27]

23.03.01 Time limit for filing an application for reissue

April 2017

Subsection 47(1) of the *Patent Act* requires that a patent be surrendered within four years from its date of grant in order to obtain a reissue. This has been interpreted as requiring that an application for reissue be filed within four years from the grant of the original patent.[28] The surrender of the original patent referred to in subsection (1) is considered to take place at the time the application for reissue is submitted in accordance with Form 1 of the Rules, but only to take effect if a new patent is issued.

The original patent should never be returned to the Office for the purpose of a reissue.

23.03.02 Patent must be "defective or inoperative"

April 2018

Pursuant to subsection 47(1) of the *Patent Act*, the Commissioner may cause the issue of a new or amended patent (a "reissue patent") whenever a patent is deemed "defective or inoperative". At a minimum, this means that, due to some error, the original patent failed to fulfil the applicant's intent upon grant.[29] As a result, the patentee has been granted a patent that fails to represent that which the applicant truly intended to have been covered and secured by it. The words "defective or inoperative" in the sense used in subsection 47(1) of the *Patent Act* do not equate to a "defect" in relation to the compliance of a patent with the *Patent Act* and *Rules* for validity purposes. A patent may be valid in all other respects, yet nonetheless fail to express what the applicant had intended.

Under subsection 47(1) of the *Patent Act*, there are two reasons why a patent can be deemed defective or inoperative: (1) insufficient description and specification; and (2) the patentee having claimed more or less than the patentee had a right to claim as new. Thus, the "defectiveness or inoperability" of the patent potentially affects the scope of protection of the patent or how well the patent describes the invention.

The words "defective or inoperative", however, do not encompass the reissue of a patent that has been judicially declared invalid,[30] or a patent for which all rights have lapsed.

An application for reissue is not a means for reopening the prosecution and permitting a patentee to amend a patent as they would amend a patent application during its normal prosecution.[31] Nor does it permit a patentee to unilaterally narrow the scope of protection as would filing a disclaimer—an application for reissue must satisfy the requirements of subsection 47(1) of the *Patent Act*.

23.03.02*a* The error and the intent of the applicant

December 2015

The reissue provision exists to correct an "error" that "arose from inadvertence, accident or mistake, without any fraudulent or deceptive intention" (subsection 47(1) of the *Patent Act*). Such an error must be one whereby the patent for which reissue is sought fails to express the intended invention;[32] that is the patent fails to state something or misstates something.

A patentee seeking reissue must show that due to "inadvertence, accident or mistake" a result that was other than what was intended by the applicant – as of the date of issuance – occurred. Mere support in the original patent for the proposed amendments is insufficient to establish intent.[33] The patentee must establish that the issued patent does not accurately express the applicant's intention with respect to the description and specification of the invention. Similarly, in cases where an original patentee has assigned his right to a patent, the assignee must still establish that the issued patent does not accurately express the intent of the applicant of the original patent. In all cases, if it is obvious that the intent of the applicant was completely fulfilled, a reissue is not justified.[34]

This is usually the most difficult part of the reissue provisions to satisfy, as there must be evidence that an error did in fact occur during the prosecution of the original patent. There also must be evidence of *what* the applicant had intended the original patent to say.

Mere allegation of an error is not evidence of that error. It is not evidence from which the Commissioner or a court can conclude that an error was made.[35]

It is the evidence as a whole that is considered; such evidence can include, for example, the text of the patent itself, evidence of actions taken during the prosecution of the original patent application[36] and of corresponding patent applications in this and other jurisdictions[37] and evidence of communications indicating intended actions that were never taken, etc. To be of practical use, the evidence must pre-date the issuance of the original patent.[38]

The onus lies with a patentee to prove that an error occurred during the prosecution of the patent application through inadvertence, accident or mistake; the extent of prior patent experience of the applicant/authorized correspondent may be taken into consideration.[39] It is presumed that the applicant's intent has been fulfilled by the issued patent,[40] which presumption may be rebutted by sufficient evidence to the contrary. For example, a patentee may allege that certain claims were cancelled from an application by mistake, but the record may show that this was done in the face of an identified defect from an examiner or to avoid conflict or to avoid prior art.[41] Unless a patentee can prove that such an action was not to have been taken, it is presumed to be indicative of the applicant's intent.

The intent has to be that of the applicant, but the error could have been made or caused by anyone (which can include the patent agent or authorized correspondent) during prosecution of the original patent.[42]

A mistake in interpreting the law may lead to an error in a patent. However, in order to fall within subsection 47(1) of the *Patent Act* such an error must have led to a patent which fails to represent the applicant's intent.[43]

23.03.03 Insufficient description and specification

December 2015

A patent defective or inoperative for insufficient description and specification is one lacking textual or graphical matter or including the wrong textual or graphical matter, contrary to the intent of the inventor upon grant. A failure to: accurately claim or describe the invention; claim subcombinations; include dependent claims; or, include claims to different categories of invention could be indicative of a patent defective or inoperative for insufficient description and specification.

23.03.04 Claiming more or less

December 2015

A patent defective or inoperative by reason of the patentee claiming more or less than he had a right to claim as new is one that results in the claims protecting more or less subject-matter than the patentee had intended. Since the description and drawings affect the scope of the claims, an error involving these parts of the patent could also result in the patent being defective or inoperative for claiming more or less than the patentee had a right to claim.

23.03.05 Same invention

December 2015

Whatever defect a patentee seeks to rectify in the patent by an application for reissue, any "amended description and specification" made by the patentee must be directed to the "same invention ... for which the original patent was granted" (subsection 47(1) of the *Patent Act)*.

Although section 38.2 of the *Patent Act* does not apply to the reissue process, its requirements (see chapter 19 of this manual) are considered to be analogous to those of subsection 47(1) for a reissued patent to be for the "same invention".

Accordingly, all matter in a reissued patent must find support somewhere in the description, drawings or claims of the original patent.[44] However, there is no requirement that an invention sought to be protected by reissue need be directed to the same inventive concept as the claims of the original patent.[45]

Subject-matter sought to be added that is inferable from the original description, drawings or claims would comply with the "same invention" requirement of subsection 47(1) of the *Patent Act*.[46] Matter that is admitted to be prior art would be acceptable as well.[47]

23.03.06 The application for reissue

April 2017

An application for reissue must include a Form 1 of Schedule I of the *Patent Rules*, completed as per the instructions (section 43 of the *Patent Rules*). Sections 3, 4 and 5 of Form 1 set out the patentee's case for granting a reissued patent. The application for reissue must also include an amended description, set of drawings and/or set of claims. All changes introduced by the amendments must be consistent with the defects identified in Form 1..[48] The patentee should also submit the most relevant available evidence (see section 23.03.02a of this manual).

The original patent should never be returned to the Office for the purpose of a reissue.

23.03.06*a* Form 1 of Schedule I

December 2015

In section 3 of Form 1 the patentee must identify specifically how the patent is defective or inoperative. This discussion can refer to problems with the claims, description or drawings. The issues must be linked with an insufficiency of description and specification or the patentee having claimed more or less than he had a right to claim as new (see sections 23.03.03 – 23.03.04 of this manual).

Section 4 of Form 1 must illustrate how the error arose which led to the patent specifying something other than what was intended. It is here that the patentee must demonstrate that an error occurred, in the sense that the patent document does not accord with the intent of the applicant.[49] (see section 23.03.02*a* of this manual). Section 4 of Form 1 should refer to any applicable submitted evidence when explaining how the error arose and how the patent document does not accord with the intent of the applicant.

Section 5 of Form 1 details when and how the patentee became aware of the error leading to the application for reissue. The error must have been discovered after the patent was issued.[50] since if an applicant allowed a patent to grant with full knowledge that an error had occurred during the prosecution, such an act would normally be taken as a deliberate one and thus as reflecting the applicant's intent. In some cases wherein the discovery of the error occurred after payment of the final fee but before issue of the patent an application for reissue may also be acceptable given an appropriate explanation. Note that the circumstances described in section 5 of Form 1 may also be relevant to the determination of whether the applicant's intent was truly unfulfilled by the original patent.

23.03.07 Examination of an application for reissue

April 2018

Unlike disclaimers, an application for reissue can result in the widening of a patent's scope; the scope of protection can be increased, thereby affecting the bargain with the public. The

Patent Office must therefore examine and approve any application for reissue..[51]

Given the retroactive effect of reissued patents (subsection 47(2) of the *Patent Act*), it is important to ensure that an application for reissue meets the requirements of section 47 of the *Patent Act*..[52] The Reissue Board, consisting of senior patent examiners from the various examination disciplines, oversees the complete application for reissue process and is tasked with ensuring that applications for reissue meet those requirements.

For any submitted application for reissue the Reissue Board first verifies that the application for reissue complies with the requirements of section 47 of the *Patent Act* as detailed in sections 23.03.02-23.03.05 of this manual. This verification will involve a review of the application, proposed amendments and submitted evidence as well as the record of prosecution in the Patent Office and, if applicable, foreign patent offices. If the application complies with the requirements then an examiner of the relevant art verifies that the reissued patent would comply with the rest of the *Patent Act* and *Rules*. This verification is analogous to the examination of a patent application and may identify any defect that would be applicable during said examination.

If the Reissue Board or examiner finds the application for reissue to be noncompliant with the *Patent Act* and *Rules*, an office letter explaining why will be issued. The patentee may respond by arguing and clarifying points, providing further evidence (which will be put on file), and/or by amending the proposed description, drawings and/or claims. The response should address the issues identified in the office letter.

However, sections 3 to 5 of Form 1 may not be amended other than to correct obvious typographical errors; section 47 of the *Patent Act* does not permit amendments to Form 1 that change the reasons for reissue.

If an impasse is reached between the patentee and the Reissue Board or the examiner, the application for reissue may be referred to the Patent Appeal Board, who will make a recommendation to the Commissioner of Patents.

A patentee should present the best evidence upon filing Form 1. All issues and evidence should be before the Reissue Board and examiner prior to any referral to the Patent Appeal Board. Further, before an application is forwarded to the Patent Appeal Board, all deficiencies therein with regards to the *Patent Act* and *Rules* must have been identified by the Reissue Board and examiner, even if an impasse occurs in the initial stage of examination before the Reissue Board.

An application for reissue does not go abandoned for failing to respond to an office letter within a certain time period, and thus there are no corresponding reinstatement fees. On the other hand, failure to respond in a timely manner can result in the application for reissue being forwarded to the Patent Appeal Board and the Commissioner of Patents.

A patentee may always end prosecution by withdrawing the application for reissue.

If the application for reissue is found acceptable by both the Reissue Board and the examiner, the patent will be reissued with an "E" document code. If the original patent was issued on the basis of an application filed after October 1, 1989 then the reissued patent will have the same patent number as the original patent; original patents issued on the basis of applications filed before said date will be reissued with a new patent number in the one million series. If the application for reissue is found acceptable the Office will send the patentee the new patent.

23.03.08 Multiple applications for reissue

April 2018

A patentee may file separate applications for reissue in respect of distinct parts of the invention covered by the original patent being reissued (subsection 47(3) of the *Patent Act*). This could result in multiple reissued patents. As with other applications for reissue, each separate application must be filed within four years of the original grant date. The separate applications for reissue must all have been filed before the effective date of surrender of the original granted patent, i.e. before the grant of a reissued patent based on any one of them.

This subsection is permissive in that it allows the patentee to file multiple applications for reissue. The Commissioner of Patents will not call for division of an application for reissue, whether the granted patent appears to have been granted with more than one invention, or an additional invention is being claimed by reissue so that the reissue will contain more than one invention. Under 36(2.1) of the *Patent Act*, the Commissioner can only call for division of a patent application before the issue of a patent on the original application. Similarly, subsections 36(2), 36(3) and 36(4) of the *Patent Act* also do not apply to applications for reissue.

Each separate application for reissue under subsection 47(3) of the *Patent Act* must be independently patentable as covering separate inventions in order to ensure that double-patenting does not arise. Where multiple applications for reissue co-exist for the same patent, yet do not cover separate and distinct parts of its invention, only one reissued patent (at most) can be granted.

While separate applications for reissue may be filed under subsection 47(3) of the *Patent Act*, the requirements of subsection 47(1) of the *Patent Act* must still be met in order to justify reissue. That is, an error must have occurred which led to the intent of the applicant of the original patent not having been fulfilled, which now results in the necessity of two or more separate reissued patents.

23.03.08*a* Examination of multiple, co-existing applications for reissue

April 2018

A situation could arise in which one or more co-existing applications for reissue are considered compliant with the *Patent Act* and *Patent Rules*, but at least one co-existing application for reissue for the same patent is refused by the Commissioner of Patents or withdrawn by the patentee. If applicable in such a case, the patentee will be notified that they may, if desired and before the expiry of a specified time limit, introduce subject-matter that appears in the refused or withdrawn application for reissue into one of the compliant applications for reissue as long as that subject-matter appeared in the original patent. If, after the introduction of subject-matter, the previously-compliant co-existing application for reissue remains compliant with the *Patent Act* and *Patent Rules*, then a patent will proceed to be reissued for the compliant applications for reissue. If the introduction of subject-matter causes the previously-compliant, co-existing application for reissue to fail to comply with the *Patent Act* and/or *Patent Rules*, then examination will continue on the previously-compliant, co-existing application for reissue until it is found to be compliant, is refused or is withdrawn. If no response is received within the specified time limit, then patents will be reissued based on the compliant applications for reissue as they exist on file in the Office.

23.03.09 Reissue of a reissued patent

December 2015

A reissued patent may itself be reissued provided that the application to reissue is filed within four years of the date of grant of the original patent (not of the reissued patent), and provided that the invention sought to be protected by reissue is directed to the same invention for which the original patent was granted.

23.03.10 Effect of a reissued patent

April 2018

The effect of reissue is retroactive and rights exist with respect to the reissued patent as if they had been in effect as of the original grant date (subsection 47(2) of the *Patent Act*).

A reissued patent may not be withdrawn after it has been issued in favour of the original patent.

Any pending action is not affected by a reissue "to the extent that its claims are identical with the original patent" (subsection 47(2) of the *Patent Act*). In this context "identical" is taken to mean "of the same scope".[53]

No additional maintenance fees apply to an application for reissue (subsections 100(2), 155(2) and 182(2) of the *Patent Rules*). However, maintenance fees remain payable on the original patent until it reissues (if it reissues), and then become payable on the reissued patent under the same conditions as the original patent (subsections 101(1),(2), 156(1), (2) and 182(3), (4) of the *Patent Rules*), that is, in accordance with the maintenance fee due dates that apply to the original patent (see chapter 24 of this manual).

23.03.11 Appeal from a refusal to grant a reissue

December 2015

Although not explicitly provided by the *Patent Act*, a refusal to grant a reissue by the Commissioner of Patents is subject to appeal to the Federal Court under section 41 of the *Patent Act*.[54]

23.04 Clerical error corrections under section 8 of the *Patent Act*

December 2015

A clerical error is an error that arises in the mechanical process of writing or transcribing.[55]

Clerical errors in any instrument of record at the Patent Office may be corrected at the discretion of the Commissioner under the provisions of section 8 of the *Patent Act*.[56] Instruments of record at the Patent Office include patents, patent applications, PCT national phase applications, petitions, assignments and other documents available in the Patent Office.

It is noted that clerical errors in the specification or drawings of a patent application are commonly corrected by amendment during prosecution as long as the correction fulfills the acceptable subject-matter requirements of such an amendment (see section 19.04 of this manual).

The correction of clerical errors originating from the patentee or applicant require payment of the prescribed fee (Schedule II, Part IV, Item 19 of the *Patent Rules*). The fee is levied for the processing of the request by the Patent Office and does not depend on the acceptance or refusal of the correction. Refunds of fees paid with a request for clerical error correction are not mandated by section 4 of the *Patent Rules*, but may be provided if the request for correction is not processed.

Third parties willing to point out possible clerical errors originating from the patentee or applicant should contact the patentee, the applicant or the patent agent of record.

Clerical errors originating from the Patent Office can be discovered during quality control verification, examination or other procedures at the Patent Office, or from observations made by the applicant, the patentee or a third party. Generally, the patentee or applicant will be contacted before any such clerical error is corrected. Since this type of correction arises from an internal procedure, no fee is levied. Similarly, no fee is levied for clerical errors originating from mistakes made by foreign patent offices, including international authorities.

23.04.01 Requesting correction of a clerical error under section 8

There is no form for requesting the correction of clerical errors under section 8 of the *Patent Act*. The patentee or applicant requests the correction by:

- describing the corrections being sought in a letter to the Commissioner, with reference to the patent or application number and the instrument of record to be corrected;
- explaining the circumstances that led to the error that may justify why the error is clerical; and,
- if the clerical error originated from the patentee or applicant, paying the prescribed fee (Schedule II, Part IV, Item 19 of the *Patent Rules*).

The grant copy of a patent should never be submitted to the Patent Office when requesting a correction.

When a clerical error request is made without the payment of the prescribed fee and the Patent Office determines that this fee is required based on the facts, the Patent Office notifies the patentee or applicant that a fee must be paid to proceed with the consideration under section 8 of the *Patent Act*.

23.04.02 Processing of a section 8 clerical error correction request

The Commissioner will review each request for correction under section 8 of the *Patent Act* according to the circumstances of the particular case.

The Commissioner will initially determine whether or not the error is clerical in nature in an instrument of record of the Patent Office. The circumstances leading to the error detailed in the request will be used to help make this determination. Factors that will be weighed in this determination include:

- whether the document being corrected is an instrument of record at the Patent Office; and,
- whether the error has arisen out of the mechanical process of writing or transcribing; for instance errors in translation, of antecedence or of omission.[57]. generally do not arise out of the mechanical process of writing or transcribing.

If it is determined that a clerical error exists, the discretion of the Commissioner will be used in deciding whether or not to make the correction..[58]. The extent to which the requested correction affects the rights of others will be one of the factors weighed by the Commissioner in this decision.
If the error is determined to be non-clerical in nature or the Commissioner has exercised discretion in refusing to make the correction, the requester will be informed in writing of the reason(s) for the refusal to perform the correction.

If the Commissioner determines that the error is clerical and elects to make the correction, the requester is informed by an office letter that the correction has been made and receives a certificate of correction listing all the changes applied to the instrument of record. For a granted patent, the certificate of correction is accompanied by a copy of the cover page and all pages affected by the correction, each bearing the official stamp "Section 8 Correction see certificate - Correction - Article 8 voir certificat." The Patent Office records are corrected accordingly.

23.04.03 Effect of a section 8 clerical error correction

The instrument of record and the certificate of correction thereof must be read in conjunction. Since the validity of an instrument of record in the Patent Office is not affected by a clerical error therein (section 8 of the *Patent Act*), the instrument of record is deemed to have been present in the corrected form upon its submission to the Patent Office. In other words, the correction of the clerical error has effects retroactive as if the correction had been in effect as of the date that the instrument of record was filed with the Patent Office.

23.05 Clerical error corrections under section 35 of the *Patent Rules*

December 2015

A clerical error is an error that arises in the mechanical process of writing or transcribing.[59].

Clerical errors in any document relating to an application other than the specification, a drawing or a document effecting a transfer or change of name, can be corrected under section 35 of the *Patent Rules* during prosecution of the application as long as the error was that something other than what was obviously intended was written.

There is no fee associated with requests for corrections under section 35 of the *Patent Rules*.

23.05.01 Requesting correction of a clerical error under section 35

There is no form for requesting correction of a clerical error under section 35 of the *Patent Rules*. The applicant requests a correction under section 35 of the Patent Rules and describes the correction to be effected, the patent application number and the document relating to the application to be corrected.

23.05.02 Processing of a section 35 clerical error correction request

The Commissioner will review each request for correction under section 35 of the *Patent Rules* according to the circumstances of the particular case.

Based on the requested correction, the Commissioner will determine whether the correction is to an obvious clerical mistake. In doing so, the Commissioner will determine whether what is currently written in the document is obviously not what was intended and further that the correction is what was obviously intended. If there is any ambiguity about what the error should be corrected to then the error is not an obvious clerical error.

If the Commissioner determines that the error is not an obvious clerical error, then the requester will be informed in writing of the reason(s) for the refusal of the correction request.

If the Commissioner determines that the error is clerical and obvious, the requester is informed by an office letter indicating that the Office records have been corrected.

23.05.03 Effect of a section 35 clerical error correction

After correcting a clerical error in a document in a patent application under section 35 of the *Patent Rules* , the document is deemed to have been present in the corrected form upon submission to the Patent Office. In other words, the correction of the clerical error has retroactive effects as if the correction had been in effect as of the date that the document relating to an application was filed with the Patent Office.

Endnotes for Chapter 23

[1] *Hershkovitz v. Tyco Safety Products Canada Ltd.*, 2009 FC 256 at para 74 aff'd 2010 FCA 190

[2] *Monsanto Co. v. Canada (Commissioner of Patents)* (1976), 28 CPR (2d) 118 at 119

[3] *Hershkovitz v. Tyco Safety Products Canada Ltd.*, 2010 FCA 190 at para 25

[4] *Bristol-Myers Squibb Canada Co. v. Apotex Inc.*, 2009 FC 137 at para 47

[5] *Hershkovitz* (*supra* at 1) at para 75

[6] *Richards Packaging Inc v. Canada (Attorney General)*, 2007 FC 11 at para 10 aff'd 2008 FCA 4

[7] *Sanofi-Aventis Canada Inc. v. Hospira Healthcare Corp.*, 2009 FC 1077 at para 142

[8] *Hershkovitz (supra* at 1) at para 79

[9] *Hershkovitz (supra* at 1) at para 79

[10] *Hershkovitz (supra* at 1) at para 78

[11] *Hershkovitz (supra* at 3) at para 25

[12] *Hershkovitz (supra* at 1) at para 76

[13] *Hershkovitz (supra* at 1) at para 81

[14] *Sanofi-Aventis (supra* at 7) at para 111

[15] *Hershkovitz* (*supra* at 3) at para 47

[16] *Bristol-Myers Squibb* (*supra* at 4) at para 43

[17] *Hershkovitz* (*supra* at 1) at para 93*; Canadian Celanese Ltd. v. B.V.D. Co. Ltd.*, [1939] 2 DLR 289 at 294

[18] *Genencor International v. Commissioner of Patents* 2008 FC 608 at para 4

[19] *Prenbec Equipment Inc v. Timberblade Inc.* 2010 FC 23 at para 34

[20] *Genencor* (*supra* at 18) at para 38

[21] *Newco Tank Corp. v. Attorney General of Canada* 2014 FC 287 at para 34

[22] *Newco* (*supra* at 21) at para 36

[23] *Prenbec* (*supra* at 19) at para 17

[24] *Genencor* (*supra* at 18) at para 39

[25] *Farbwerke Hoechst Aktiengesellschaft vormals Meister Lucius & Bruning v. Commissioner of Patents* (1966), 50 CPR 220 at 254

[26] *Northern Electric Company Ltd. v. Photo Sound Corporation*, [1936] SCR 649 at 653; *Bergeon v. DeKermor*, [1927] 2 DLR 99 at para 38

[27] Commissioner's Decision #1330 at para 43-44

[28] *Curl-Master Manufacturing Co. Ltd. v. Atlas Brush Ltd.* (1967), 52 CPR 51 at 74

[29] *Farbwerke* (*supra* at 25) at 254

[30] *Farbwerke* (*supra* at 25) at 255; *Burton Parsons Chemicals Inc. v. Hewlett-Packard (Canada) Ltd.* (1974), 17 CPR (2d) 97 at 107; *Creations 2000 Inc v. Canper Industrial Products Ltd.* (1988), 22 CPR (3d) 389 at 406 aff'd 34 CPR (3d) 178

[31] Commissioner's Decision #1289 at para 67-68; Commissioner's Decision # 1279 at 11, 14

[32] Commissioner's Decision # 1297 at para 26, 44

[33] Commissioner's Decision #1289 at para 46

[34] *Northern Electric Company Ltd. (supra at 26*)

[35] *Paul Moore Co. Ltd. v. Commissioner of Patents* (1979), 46 CPR (2d) 5 at 10

[36] *Northern Electric* (*supra* at 26) at 654; *Mobil Oil Corp v. Hercules Canada Inc.* (1994), 57 CPR (3d) 488 at 498, 499 rev'd on other grounds 63 CPR (3d) 473; Commissioner's Decision # 1173 at 8

[37] *Mobil Oil* (*supra* at 36) at 499

[38] Commissioner's Decision #1289 at para. 41; Commissioner's Decision #1333 at para. 26

[39] *Northern Electric* (*supra* at 34) at 654; *Curl-Master* (*supra* at 28) at 68-69

[40] *Northern Electric* (*supra* at 34) at 654

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[41] Commissioner's Decision #134 at 5; Commissioner's Decision #326 at 9; Commissioner's Decision #420 at 1; Commissioner's Decision #783 at 4-5; Commissioner's Decision #906 at 10 Commissioner's Decision #1148 at 17; Commissioner's Decision #1186 at 5

[42] *Burton Parsons* (*supra* at 30) at 108

[43] *Farbwerke* (*supra* at 25) at 259

[44] *Curl-Master* (*supra* at 28) at 68, 70-71; *Mobil Oil* (*supra* at 36) at 501; Commissioner's Decision #1289 at para 21

[45] *Curl-Master* (*supra* at 28) at 68, 70-71; *Mobil Oil* (*supra* at 36) at 501

[46] *Curl Master* (*supra* at 28) at 70-71

[47] Commissioner's Decision #56 at 7

[48] *Northern Electric* (*supra* at 34) at 659

[49] *Farbwerke* (*supra* at 25) at 254

[50] Commissioner's Decision #1093 at 6-7; Commissioner's Decision #1173 at 3

[51] *Herschkovitz* (*supra* at 3) at para 24

[52] *Northern Electric* (*supra* at 34) at 652-653; *Creations* (*supra* at 30) at 406

[53] *Urea Casale S.A. v. Stamicarbon B.V.* 2002 FCA 10 at para 22

[54] *Farbwerke* (*supra* at 25) at 245-46

[55] *Bayer Aktiengesellschaft v. Commissioner of Patents* (1980), 53 CPR (2d) 70 at 73

[56] *Bayer* (*supra* at 55) at 74

[57] *Dow Chemical Co. v. Canada (Attorney General)* 2007 FC 1236 at para 26-27; *Scannex Technologies v. Canada (Attorney General)* 2009 FC 1068 at para 30

[58] *Bayer* (*supra* at 55) at 74

[59] *Bayer* (*supra* at 55) at 73

Chapter 24
Maintenance Fees

24.01
Maintenance of patent applications – June 2015

Pursuant to subsection 27.1(1) of the *Patent Act* and subsection 99(1) of the *Patent Rules*, an applicant who files a patent application in Canada must pay maintenance fees for prescribed periods in order to maintain the application in effect.

The amounts and time limits for paying maintenance fees to maintain an application in effect are listed in item 30 of Schedule II of the *Patent Rules*.

Divisional applications carry their own maintenance fees, separate from the parent application. Pursuant to subsections 99(2) and 154(2) of the *Patent Rules*, maintenance fees will be calculated from the filing date of the parent application and are payable upon filing of the divisional application. For example, if a divisional application is filed 40 months after the parent application, maintenance fees for the 2nd and 3rd years have to be paid upon filing of the divisional application.

Applications filed under the provisions of the Patent Cooperation Treaty and entering the national phase in Canada must pay maintenance fees in accordance with part VI of Schedule II of the *Patent Rules*. It should be noted that the international filing date is the date on which the maintenance fee schedule is based.

24.01.01
Due dates for application maintenance fees

For maintaining an application filed on or after October 1, 1989, an applicant must pay maintenance fees for each one-year period from the second anniversary of the filing date of the application.

The maintenance fee for an application must be paid before the first day of the one-year period the fee covers. For example, the maintenance fee covering the one-year period ending on the fifth anniversary of the filing of the application must be paid on or before the fourth anniversary of the filing date.

Any or all of the maintenance fees for a particular application may be paid in advance.

In accordance with sections 102 and 157 of the *Patent Rules*, the time limits for payment of application maintenance fees cannot be extended.

24.01.02
Late and non-payment of application maintenance fees

If the maintenance fee on a patent application is not paid on or before the anniversary date the application will become abandoned pursuant to paragraph 73(1)(*c)* of the *Patent Act*. The application, however, may be reinstated if there is a clear request for reinstatement and payment is made within the one-year period following the due date along with the prescribed reinstatement fee listed in item 7 of Schedule II of the *Patent Rules*. If the one-year period for reinstatement has expired before payment of both the maintenance fee and the reinstatement fee, or before a request for an extension of the reinstatement period is made (subsection 26(1) of the *Patent Rules*), the application can never be reinstated (see Chapter 20 of this manual).

24.01.03
Responsibility for payment of maintenance fees for applications

The authorized correspondent is the only person entitled to pay the maintenance fees for patent applications.

As a courtesy, the Office will send a reminder to the authorized correspondent that the payment of the first maintenance fee is approaching. This will be a one-time courtesy notice mailed approximately three months in advance of the second anniversary of the application's filing date.

In the case of an abandoned application, the Office will also send a courtesy notice to a private inventor (no patent agent has been appointed) that the expiry of the time limit for reinstatement of an abandoned application is approaching. This will be a courtesy notice mailed approximately three months prior to the expiry of the time limit for reinstatement of an abandoned application.

It is always the responsibility of the authorized correspondent to ensure the timely payment of maintenance fees. As notices sent to the authorized correspondent are sent as a courtesy only, consequences for non-payment arise even if a notice is not sent.

24.02
Maintenance of patents – June 2015

Pursuant to subsection 46(1) of the *Patent Act* and subsection 100(1) of the *Patent Rules*, a patentee must pay maintenance fees for prescribed periods in order to maintain the rights accorded by the patent.

The amounts and time limits for paying maintenance fees to maintain the rights accorded by a patent are listed in items 31 and 32 of Schedule II of the *Patent Rules*.

No maintenance fee for a patent is due for any period where a maintenance fee was paid to maintain the corresponding patent application in effect.

Maintenance fees for reissue patents are due at the same times and for the same periods as the original patent for the unexpired term of the original patent. No fee to maintain the rights accorded to a reissue patent is payable for any period where a maintenance fee was paid to maintain the original patent or to maintain the application for the original patent (subsections 101(2), 156(2) and 182(4) of the *Patent Rules*).

In accordance with subsections 100(2), 155(2) and 182(2) of the *Patent Rules*, maintenance fees do not have to be paid on an application for reissue of a patent. However, the patentee must continue to pay maintenance fees on the original patent that is the subject of the application for reissue.

24.02.01
Due dates for patent maintenance fees

For maintaining the rights accorded by a patent issued on the basis of an application filed on or after October 1, 1989, maintenance fees will continue to be due on the same payment schedule until the last payment is made before the nineteenth anniversary of the filing date.

For maintaining the rights accorded by a patent on the basis of an application filed before October 1, 1989, an applicant must pay maintenance fees for each one-year period from the second anniversary of the day on which the patent was issued until the last payment is made before the sixteenth anniversary of the issue.

In accordance with sections 102 and 157 of the *Patent Rules*, the time limits for payment of maintenance fees for patents cannot be extended.

24.02.02
Late and non-payment of patent maintenance fees

If the maintenance fee on a patent is not paid on or before the anniversary date, the patent is now considered to be in an "about-to-lapse" state. Unless the maintenance fee and an additional fee for late payment are paid within one year following the anniversary date, the patent (subsections 100(1), 155(1) and 182(1) of the *Patent Rules*) or reissued patent (subsections 101(1), 156(1) and 182(3) of the *Patent Rules*) will lapse.

A lapsed patent cannot be revived (see Chapter 20 of this manual). Pursuant to subsection 46(2) of the *Patent Act*, a patent is deemed to have lapsed at the expiration of the time specified in items 31 and 32 of Schedule II of the *Patent Rules* for payment of maintenance fees.

24.02.03
Responsibility for payment of maintenance fees for patents

Following the grant of a patent, the fee to maintain the patent can be paid by the patentee, or by any person acting for the patentee (e.g. authorized correspondent, owner, inventor, clearing house, etc.), whether residing in Canada or not.

If the patentee is a private inventor (no patent agent has been appointed) the Office will send a reminder that the date for the payment of a maintenance fee is approaching. A courtesy notice will be mailed approximately six months prior to the anniversary date, and another notice will be mailed three months prior to the anniversary date or the patent's issue date, if applicable.

If the patentee is Canadian and an agent has been appointed, the Office will send a courtesy notice to the agent and a copy to the patentee informing them that the patent is now in an "about-to-lapse" state for failure to pay the maintenance fee by the due date.

In cases where the patentee is not Canadian and an agent has been appointed, the Office will send the "about-to-lapse" notice to the authorized correspondent only.

Notices are sent as a courtesy only and consequences for non-payment arise even if a notice is not sent.

24.03

Maintenance fee information on the Canadian Patent Database – December 2015

Maintenance fee information is accessible on the administrative status page (select "Admin Status" tab) for all patent applications and patents listed in the Canadian Patent Database (CPD).

Maintenance fee information includes the date and amount of the last payment received, the date and amount of the next payment if the applicant or patentee is a small entity type and the date and amount of the next payment if the applicant or patentee is a standard entity type.

It should be noted that the CPD is for information purposes only. For legal purposes, it is recommended that the relevant documents in the Patent Office be consulted.

Chapter 25
Tariff of Fees

25.01 Tariff of fees – June 2016

Schedule II of the Patent Rules sets out the various fees that must be paid to the Commissioner of Patents in respect of proceedings taken or services requested under the Patent Act. A summary of these fees is also available on CIPO's web site.